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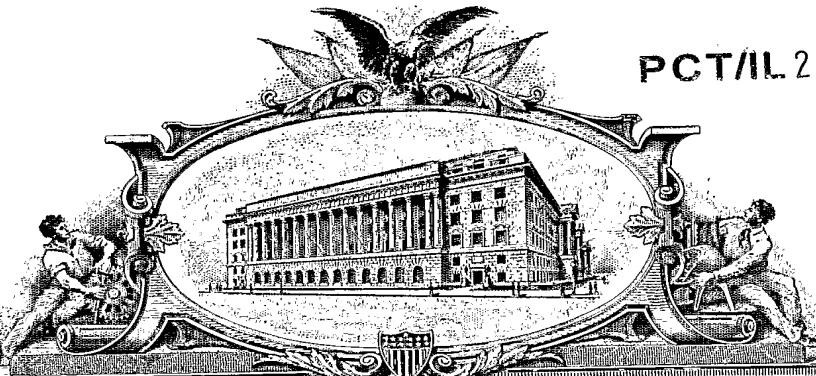
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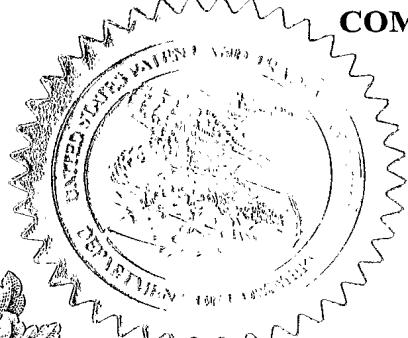
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## PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (b)(2).

Docket Number

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13441 U.S. PTO  
60/541447

022604

### TITLE OF THE INVENTION (280 characters max)

DILATATION BALLOON CATHETER INCLUDING EXTERNAL MEANS FOR  
ENDOLUMINAL THERAPY AND FOR DRUG ACTIVATION

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### ENCLOSED APPLICATION PARTS (check all that apply)

<input checked="" type="checkbox"/> Specification	Number of Pages	48	<input checked="" type="checkbox"/> Applicant is entitled to Small Entity Status
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	33	<input checked="" type="checkbox"/> Other (specify) 2 claims

### METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)

<input type="checkbox"/> A check or money order is enclosed to cover the filing fees	<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number: 50-1407	FILING FEE AMOUNT (\$)	\$ 80.-
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

No

Yes, the name of the US Government agency and the Government contract number are: \_\_\_\_\_

Respectfully submitted,

SIGNATURE Sol Sheinbein

24 February 2004

Date

25,457

REGISTRATION NO.  
(if appropriate)

TYPED or PRINTED NAME SOL SHEINBEIN

Additional inventors are being named on separately numbered sheets attached hereto

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## **Dilatation balloon catheter including external means for endoluminal therapy and for drug activation**

### **FIELD OF THE INVENTION**

Embodiments of the present invention relate to a dilatation balloon catheter to be used in vascular interventions or other similar interventions such as treatment of stenosis in the biliary system, the urinary system or the gastrointestinal system. The disclosed dilatation balloon catheter includes optical and mechanical means to facilitate percutaneous endoluminal therapy of blood vessels or other anatomical structures according to the clinical application. The endoluminal therapy is achieved through a combination of very confined radial light energy delivery and mechanical effects. Additionally, the design of the disclosed dilatation balloon catheter facilitates its advancement and maneuvering through tortuous anatomical structures such as stenotic or partially occluded blood vessels to facilitate its optimal positioning even in the most challenging clinical conditions. The present invention also relates to a dilatation balloon catheter including means to facilitate endoluminal drug activation. Embodiments of the current invention describe a dilatation balloon with means for Photodynamic Therapy, wherein light activated drugs are used to treat cardiovascular, benign and malignant stenosis and other diseases. Additional therapy endoluminal means and methods are also disclosed in various embodiments. The disclosed invention is particularly useful, but not limited to treatment of blood vessel diseases or diseases of other similar anatomical structures.

## BACKGROUND OF THE INVENTION

Percutaneous transluminal angioplasty (PTA) using a dilatation balloon catheter remains the most effective and widely used interventional endoluminal technique in treatment of stenosis in the vascular, biliary and urinary system. Percutaneous transluminal coronary angioplasty is further referred as PTCA. Inflation of an angioplasty balloon in a stenotic artery, for example, causes splitting or dissection of the atherosclerotic plaque and adjacent intima, and stretching of the muscularis media, thus increasing the cross-sectional area of the artery. After the intervention, the intima re-endothelializes as part of the remodeling process. Three of the main obstacles faced by conventional PTA in cardiovascular applications are:

- Difficulty of dilating rigid, elastic or diffusely diseased segments;
- Difficulty of preventing or reversing abrupt closure of the dilated segment;
- Virtually inability to reduce below 30% - 40% the incidence of restenosis after successful expansion of the blood vessel lumen (without using additional therapy means such as stenting).

In order to improve clinical results in cardiovascular applications, the dilatation of a blood vessel lumen by inflating a dilatation balloon catheter is followed by stenting in more than 90% of the currently performed PTA/PTCA procedures. However, clinical data shows that restenosis or distal embolization occurs in 10% to 30% of cases even after placement of a balloon expandable or self-expandable regular stent. In such cases, it is necessary to treat the stenotic area again, and PTA/PTCA is often chosen as the preferred way of re-canalizing the restenotic segment.

Over the years several adjacent mechanisms were added to the original PTA/PTCA aperture in order to improve the dilatation mechanism of the basic dilatation balloon catheter. These mechanisms include (among others):

- Addition of very small metal blades on the perimeter of the basic balloon body in order to create during the inflation small cuts in the atherosclerotic plaque - US Patent No. 5,320,634 (Virgil et all.). These cuts are intended to assist during the splitting and dissection process. The length of such blades is significantly limited due to maneuvering constraints and safety issues.

- Addition of metal wire/s on the perimeter of the basic balloon body in order to apply a concentrated stress on the atherosclerotic plaque and on the blood vessel lumen wall during dilatation -- US Pat. No. 6,394,995 (Solar et all.).

References have been made in the literature regarding the usage of lasers for endoluminal therapy purposes. Most of the references are related to laser delivery means capable of emitting forward focused light directed to open an occluded vessel lumen. Other described laser delivery means - see for example, US Pat. No. 5,446,234, US Pat. No. 5,741,246, US Pat. No. 5,891,082, US Pat. No. 6,159,236 and US Pat. No. 6,485,485 - use lateral transmission of light from the inside of the basic balloon body through a transparent balloon material for healing purposes after the inflation process. Spears et all. describe in US Pat. Nos. 5,226,430 and 5,019,075 the option of heating the region surrounding a balloon used for PTCA by means within the balloon or within the skin of the balloon in order to fuse together fragmented segments of tissue. In U.S. Patent 5,624,433, Radisch describes the usage of grooved laser rods for using light incision while dilating a balloon. The grooved laser-rods described by Radisch, if used, would cause severe collateral thermal damage due to their inherent low efficiency and therefore lead to an unwanted high-level of restenosis.

Alternative referenced therapy methods employ ionizing radiation (such as X-Ray) delivery to the required blood vessel area (also referenced as brachytherapy means).

An alternative method for decreasing the restenosis rate is the usage of drugs that prevent cell proliferation and assist in the healing process. The most prominent device based on this therapy effect is the new generation of "Drug-Eluting Stents" that has currently been developed by various companies. Drug Eluting Stents are stents coated with special drugs that are slowly released in the vessel wall in order to prevent cell proliferation (after stenting) thus preventing possible in-stent restenosis. Preliminary results show that even after usage of Drug Eluting Stents the rate of in-stent restenosis is much lower, but can still be above 8% depending on the type of patients and lesions (diabetic/non-diabetic, etc).

Alternative methods for delivering and activating drugs that are efficient in preventing restenosis are developed/disclosed by several other companies. One of the proposed methods is Photodynamic Therapy (PDT) wherein light activated drugs are used to locally and selectively prevent or treat restenosis. U.S. Patents Nos. 5,997,570

and 6,159,236 describe balloon catheters with light sources inside the balloon for performing Photodynamic Therapy.

It is the purpose of the current invention to improve existing PTA/PTCA techniques and provide to the basic PTA apparatus additional means and capabilities that will improve the clinical outcome and long-term results of PTA. Particularly, it is the purpose of the current invention to disclose the addition of radial confined light energy delivery means, where said energy delivery means ensure a smooth dilatation of a stenotic lesion through a combination of light-energy and mechanical means, and are capable of creating longitudinal microscopic cuts or cracks around the energy delivery means without damaging the vessel wall and without inducing undesirable collateral thermal damage to the vessel tissue. It is also the purpose of the present invention to describe methods and apparatus for decreasing the pressure required during the dilatation of the balloon in order to reduce the stress to the vessel wall that is of particular importance in reducing restenosis. It is also the purpose of the current invention to disclose efficient means for activating photosensitive drugs during an angioplasty procedure. All the means and methods disclosed in the current invention are meant to overcome the clinical limitations of existing PTA/PTCA procedure.

The disclosed endoluminal therapy apparatus and methods can be used in treatment of stenosis, re-stenosis and in-stent restenosis, and are particularly effective in preventing acute and late restenosis. The apparatus and methods disclosed can preclude the usage of endoluminal stents or can be used as an adjunct to stenting. The apparatus and methods described are equally useful in assisting primary-stenting diminishing clinical complications that might be associated with such a procedure.

The current invention is also applicable to other clinical applications such as treatment of other various cardiovascular, and nonvascular diseases.

## SUMMARY OF THE INVENTION

Throughout the document *light* means an electro-magnetic wave of various wavelength from 0.2 micron (UV) and up to 12.0 micron (IR). Throughout the document *light energy delivering elements* refer to optical fibers, hollow glass waveguides, photonic crystal fibers or other light-conductive means that may be used to deliver light or light energy to a required position in the body in relation to the present invention. Throughout the document a *light source* refers to any possible means of generating light or light energy, such as solid-state lasers, diode-lasers, gas-lasers, fiber-lasers, etc.

The present invention discloses apparatus and methods for treating a stenotic lesion in a vessel or similar clinical conditions. A dilatation balloon catheter includes external means of emitting energy in a radial direction. The chosen emitting means, the energy type, the waveform and the intensity level enable to select an interaction depth between the radial emitted energy and the plaque/tissue in a preferred range between 1 to 120 microns, without inducing thermal damage to tissue beyond this volume. The radial energy emission is activated during the dilatation of the balloon body while the dilatation of the balloon constantly brings the external radiating means in contact with the stenotic plaque or other type of tissue. The emission is selective and can be activated only at the beginning of the dilatation or during the entire dilatation process. The emission is ceased (automatically, semi-automatically or manually) when the dilatation has reached a certain level. The emission can optionally be matched (automatically, semi-automatically or manually) to the type of tissue proximal to the emitting means according to available information regarding the type of tissue. The dilatation balloon catheter also includes means of exerting focused pressure on the same volume of tissue that interacts with the energy. The resulting opto-mechanical or thermo-mechanical effects cause removal or cracking or weakening of segments of microscopic width in the plaque or in the adjacent tissue, without inducing any thermal damage to the vessel tissue. The dilatation balloon catheter is preferably made from semi-compliant or non-compliant material, and its size is selected to dilate a stenotic lesion at lower pressure – typically between 2 to 6 atmospheres, and preferably between 2 to 4 atmospheres. If the balloon is

manufactured from semi-compliant material, at any pressure level in a specified range the balloon will be able to increase its diameter by preferably 10%-15%. Optionally, the balloon will have a inflation range where it acts as a semi-compliant balloon and an inflation range where it acts as a non-compliant balloon, in order to ensure that there is a pressure range where the balloon inflation can benefit from the described opto-mechanical or thermo-mechanical effects induced by the radiating means, and at the same time there is no danger of over-stretching or inducing unwanted thermal or other damage to the vessel wall.

The inflation rate is gradual and matched to the effect induced by the radial emitting means and/or to the opto-mechanical or thermo-mechanical effects. The gradual inflation is preferably automatic or semi-automatic and correlated to the size and material from which the balloon is manufactured, to the change in the size and to the pressure level.

A first embodiment of the current invention discloses a dilatation balloon catheter with 1 to 4 optical fibers disposed longitudinally on the basic balloon body each optical fiber having a distal section capable of emitting radial light-energy in at least one radial direction. The mechanical attachment of the optical fibers on the catheter ensures that the distal radial emitting section remains on the same position on the basic balloon body regardless of the inflation/deflation stage of the balloon and ensure that it remains in contact to the vessel wall and/or the stenotic tissue that may be covering it at all the stages during the inflation of the balloon. The mechanical attachment of the optical fibers also ensures the proper deployment and re-wrapping of the optical fibers during the inflation/deflation of the dilatation balloon. Before, during or after the dilatation of the dilatation balloon catheter, the externally attached optical fibers emit light energy through the distal section in a radial direction, where the radial emission pattern is substantially uniform along the entire emitting section. The design of the optical fibers ensures a high level of efficiency, in order to minimize the amount of heat dissipated to adjacent tissue, to minimize the size of the laser source and to minimize the required energy level through the fibers, therefore reducing the potential damage to the fibers. The selected wavelength, light waveform and intensity ensure that the interaction between the radial emitted light-energy and the plaque/tissue occurs only within a small volume of tissue adjacent to the emitting section without inducing thermal damage to the vessel wall. The interaction depth is typically selected between 1 to 120 microns, and preferably between 10 to 50

microns, without inducing thermal damage to tissue beyond this volume. Optionally, the wavelength is selected according to specific cromophores in the tissue, or specific cromophores are induced in the plaque or adjacent tissue in order to increase the absorption coefficient at a selected wavelength. During the inflation of the balloon, the externally attached optical fibers pressure the exact longitudinal microscopic region that interacted with the radial confined light-energy delivery. Therefore, during the inflation process, the radial emitting section induces combined opto-mechanical effects into the adjacent tissue without causing collateral thermal damage, and facilitates the splitting of the atherosclerotic plaque or thrombosis.

For optimal clinical results, the rate of increasing the pressure within the dilatation balloon has to be matched to the opto-mechanical effect induced by the external light-delivery means (by methods disclosed in the present invention) ensuring that the dilatation of the vessel wall is made at a minimal pressure, and taking full advantage of the microscopic longitudinal opto-mechanical effects. As taught in the present invention, the material, the design and the size of the dilatation balloon body are selected such that it reaches the required diameter at significantly lower pressures than usual dilatation balloons (based on the fact that the dilatation process is assisted by the opto-mechanical effect created by the external light-delivery means).

Other embodiments of the current invention disclose alternative means of inducing microscopic opto-mechanical effects capable of assisting the dilatation of a stenotic area based on alternative combinations of light-energy delivering and mechanical means.

The light-energy delivery means externally attached to the dilatation balloon catheter as disclosed in the above embodiments have additional clinical advantages due to their increased maneuverability inside the vessel lumen, and due to the capability of using virtually any length of the therapeutic length, as opposed to safety constraints on the lengths of possible alternative sharpened structures - see for example the atherotomes described by Virgil at all in US Patent No. 5,320,634.

Other embodiments of the current invention disclose apparatus and methods of using the light energy means externally attached to the dilatation balloon catheter for controlled delivery and activation of photosensitive drugs. In cardiovascular applications, for example, the external light delivery means can emit radial light energy that activates light sensitive drugs during and/or after the inflation of the dilatation balloon catheter and remodeling of the blood vessel wall. The activation of

the light sensitive drugs that are effective in preventing or treating restenosis can be used as stand-alone therapy or by using the same light energy means and light source can be adjacent means to the opto-mechanical effect described in the first embodiment that creates cuts or cracks in the stenotic tissue and assists the dilatation process.

According to the present invention the same dilatation balloon catheter including light energy delivering elements and the same light source can be used to achieve multiple therapy effects based on variations of wavelength, duration or energy level of the delivered light energy.

Additional embodiments of the current invention disclose alternative apparatus and methods including optimal combinations of radial confined light energy means and mechanical effects that are added to a dilatation balloon catheter in order to improve endoluminal therapy effects, and particularly in order to facilitate the dilatation of the stenotic segment at significantly lower pressures than regular dilatation balloon catheters, without inducing collateral thermal damage to the vessel wall.

Additional embodiments of the current invention disclose alternative apparatus and methods including optimal combinations of radial confined energy means and mechanical effects that are added to a dilatation balloon catheter in order to improve endoluminal therapy effects, and particularly in order to facilitate the dilatation of the stenotic segment at significantly lower pressures than regular dilatation balloon catheters. Energy means include cryogenic means, thermal or other energy means.

A more complete understanding of the microscopic opto-mechanical/thermo-mechanical blades attached to a dilatation balloon catheter and of the drug activation mechanism disclosed by the current invention and of the clinical advantages offered by the disclosed apparatus and methods will be readily available to those skilled in the art by reviewing the following detailed description and preferred embodiments.

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 pictorially illustrates a first preferred form of a dilatation balloon catheter with externally attached optical delivery means according to an embodiment of the present invention.

Fig. 2a pictorially illustrates a dilatation balloon catheter with externally attached optical delivery means as illustrated in its inflated position according to a first embodiment of the present invention.

Fig. 2b pictorially illustrates a dilatation balloon catheter with externally attached optical delivery means as illustrated in its deflated position according to a first embodiment of the present invention.

Fig. 2c pictorially illustrates a modification of the bonding method of the externally attached optical delivery means.

Fig. 3a pictorially illustrates a first preferred modification of the first preferred form of a dilatation balloon catheter according to an alternative design of the first embodiment of the current invention.

Fig. 3b pictorially illustrates a second possible modification of the first preferred form of a dilatation balloon catheter according to an alternative design of the first embodiment of the current invention.

Fig. 3c pictorially illustrates a third possible modification of the first preferred form of a dilatation balloon catheter according to an alternative design of the first embodiment of the current invention.

Fig. 3d pictorially illustrates a fourth possible modification of the first preferred form of a dilatation balloon catheter according to an alternative design of the first embodiment of the current invention.

Fig. 4a pictorially illustrates the light energy delivery sub-system from light source to a set of optical fibers externally attached to a dilatation balloon catheter according to the first embodiment of the present invention.

Fig. 4b pictorially illustrates an alternative design of the light energy delivery sub-system from light source to a set of optical fibers externally attached to a dilatation balloon catheter according to an alternative design of the first embodiment of the present invention.

Fig. 5a pictorially illustrates the maneuvering and positioning of a dilatation balloon catheter with externally attached optical delivery means for a PTA procedure according to the first embodiment of the present invention.

Fig. 5b pictorially illustrates the usage of a dilatation balloon catheter with optical delivery means for a PTA procedure according to the first embodiment of the present invention.

Fig. 5c pictorially illustrates the maneuvering and positioning of a dilatation balloon catheter with externally attached optical delivery means for a PTA procedure in a blood vessel including an asymmetric stenotic area.

Fig. 5d pictorially illustrates the usage of a dilatation balloon catheter with optical delivery means for a PTA procedure in a blood vessel including an asymmetric stenotic area.

Fig. 6a pictorially illustrates a cross-section of a blood vessel lumen while using a dilatation balloon catheter with externally attached optical delivery means according to the first preferred embodiment.

Fig. 6b pictorially illustrates a cross-section of a blood vessel lumen after using and retrieving a dilatation balloon catheter with externally attached optical delivery means.

Fig. 7a illustrates the potential energy pattern of an evanescent light-wave emitted from an optical fiber into the adjacent plaque.

Fig. 7b illustrates a first possible design of an optical fiber with a light-energy emitting section capable of emitting high efficiency radial longitudinally uniform confined light energy.

Fig 7c illustrates the expected emission pattern of the radial light emitting section illustrated in Fig 7b.

Fig. 8a illustrates a first possible design of an inflation and transfer sub-system to be used in conjunction with a dilatation balloon catheter with externally attached optical delivery means.

Fig. 8b illustrates a second possible design of an inflation and transfer sub-system to be used in conjunction with a dilatation balloon catheter with externally attached optical delivery means.

Fig. 8c illustrates a third possible design of an inflation and transfer sub-system to be used in conjunction with a dilatation balloon catheter with externally attached optical delivery means.

Fig. 9 illustrates a light source design to be used in conjunction with a dilatation balloon catheter with externally attached light energy delivery means.

Fig. 10a pictorially illustrates a design for the distal part of the light energy delivery sub-system according to an alternative design of the first embodiment of the present invention.

Fig. 10b pictorially illustrates an alternative design for the distal part of the light energy delivery sub-system according to an alternative design of the first embodiment of the present invention.

Fig. 10c pictorially illustrates an alternative design for and attachable light energy delivery sub-system and externally attached optical delivery means according to an embodiment of the present invention.

Fig. 10d pictorially illustrates a dilatation balloon catheter with externally attached optical delivery means and also with internal light delivery means according to an embodiment of the present invention.

Fig. 10e pictorially illustrates a dilatation balloon catheter with externally attached optical delivery means for dilating a stenotic lesion and also for delivering a stent according to an embodiment of the present invention.

Fig. 11a pictorially illustrates a dilatation balloon catheter with externally attached optical delivery means according to a second embodiment of the present invention.

Fig. 11b pictorially illustrates a dilatation balloon catheter with externally attached optical delivery means and also with internal light delivery means according to an embodiment of the present invention.

Fig. 12a pictorially illustrates a cross-section of a dilatation balloon catheter with externally attached optical delivery means according to the second preferred embodiment of the present invention.

Fig. 12b pictorially illustrates a cross-section of an alternative design for a dilatation balloon catheter with externally attached optical delivery means according to the second preferred embodiment of the present invention.

Fig. 13a pictorially illustrates the maneuvering and positioning of a dilatation balloon catheter with externally attached optical delivery means for a PTA procedure according to the second preferred embodiment of the present invention.

Fig. 13b pictorially illustrates the usage of a dilatation balloon catheter with optical delivery means for a PTA procedure according to the second preferred embodiment of the present invention.

Fig. 14 pictorially illustrates a dilatation balloon catheter with externally attached optical delivery means according to a third embodiment of the present invention.

Fig. 15a pictorially illustrates a cross-section of an inflated dilatation balloon catheter with externally attached optical delivery means according to the third preferred embodiment.

Fig. 15b pictorially illustrates a cross-section of an alternative design of a dilatation balloon catheter with externally attached optical delivery means according to the third preferred embodiment.

Fig. 16 pictorially illustrates a dilatation balloon catheter with externally attached light-induced thermal delivery means according to a fourth preferred embodiment of the present invention.

Fig. 17a pictorially illustrates a cross-section of an inflated dilatation balloon catheter with externally attached light-induced thermal delivery means according to the fourth preferred embodiment.

Fig. 17b pictorially illustrates a cross-section of an alternative design of a dilatation balloon catheter with externally attached light-induced thermal delivery means according to the third preferred embodiment.

Fig. 18 pictorially illustrates a dilatation balloon catheter with externally attached cryogenic delivery means according to a fifth preferred embodiment of the present invention.

Fig. 19a pictorially illustrates a dilatation balloon catheter with externally attached RF-induced thermal delivery means according to a sixth preferred embodiment of the present invention.

Fig. 19b pictorially illustrates a dilatation balloon catheter with externally attached RF-induced thermal delivery means according to an alternative design of the sixth preferred embodiment of the present invention.

Fig. 19c pictorially illustrates a dilatation balloon catheter with externally attached RF-induced thermal delivery means according to an alternative design of the sixth preferred embodiment of the present invention.

### **DETAILED DESCRIPTION OF THE DRAWINGS**

In the following description, various aspects of the invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the invention. However, it will also be apparent to one skilled in the art that the invention may be practiced without the specific details presented herein. Furthermore, well known features may be omitted or simplified in order not to obscure the invention.

Throughout the document *light* means an electro-magnetic wave of wavelengths is in the range of 0.2 micron to 12 micron. Throughout the document *light delivering elements* refer to optical fibers, hollow glass waveguides, photonic crystal fibers or other light-conductive means that may be employed to deliver light to a required position in the body in relation to the present invention. Throughout the document a light source refers to any possible means of generating light energy, such as solid-state lasers, diode lasers, gas-lasers, fiber-laser, etc.

Reference is now made to FIG.1, Fig. 2a and Fig. 2b that illustrate a first embodiment of the present invention. A dilatation balloon catheter 1 to be used in vascular interventions includes a basic balloon body 2 with a set of balloon externally attached optical fibers 3 enabling the delivery of light energy to a blood vessel wall 150. An inflation system 20, enables the inflation and deflation of basic balloon body 2 by standard means such as supply or removal of liquid or gas. Basic balloon body 2

is attached to a tube-like catheter body 4 that ends in a distal catheter member 41. Tube-like catheter body 4 also includes a catheter body intermediary section 42, an optional catheter body intra-balloon section 43, and a catheter body proximal section 44.

Set of balloon externally attached optical fibers 3 is optically connected to a light source 100. Optionally, a light-energy guide system 5 is used to transfer light energy produced by a light source 100 to set of externally attached optical fibers 3. In order to achieve an optimal therapeutic effect set of balloon externally attached optical fibers 3 have a light-energy emitting section 31 capable of emitting radial light energy 105 to the contact surface with blood vessel wall 150 and/or atherosclerotic plaque 151. As furthered detailed radial emitted light-energy 105 has an energy pattern substantially uniform along light-energy emitting section 31 and a very confined interaction depth within the adjacent tissue. Preferably, light-energy emitting section 31 has a diameter of 50 to 80 microns, but other diameter can also be used according to the vessel lumen size and clinical application. Special mechanical designs to be detailed in following sections ensure that light-energy emitting section 31 is positioned at the same location on basic balloon body 2, regardless of the inflation/deflation of the balloon, and also ensure proper deployment and re-wrapping of set of balloon externally attached optical fibers 3 during the inflation/deflation of basic balloon body 2.

The design of light-emitting section 31 is matched with a proper selection of the wavelength, wave-form and intensity level of the light-energy generated by light source 100 in order to ensure that radial confined light energy 105 has only a very short interaction depth with the adjacent tissue, where the interaction depth is defined as the depth where the energy delivered to the tissue causes heating / tissue removal /vaporization /bond-weakening effects according to a clinical selected effect. A preferred range for the interaction depth of radial confined light-energy 105 in the tissue is less between 1 micron to 120 microns, and for specific vascular applications is between 1 micron to 50 microns, where tissue at a distance of more than 50 microns from the light-energy emitting section 31 is not damaged. i.e. no irreversible damage is induced on the tissue cells. Alternative designs and selection of wavelengths can ensure that the interaction depth of radial confined light-energy 105 in the tissue is less than several microns, without causing damage to tissue beyond this distance.

Avoiding thermal damage to the tissue of the vessel wall is a critical factor in reducing restenosis.

According to a first preferred option, the radial energy emitted by light-energy emitting section 31 causes a confined volume of adjacent tissue to reach a temperature of 60°C – 80°C, and in some cases above 80°C. In order to achieve this effect the preferred way is to select wavelengths with small penetration depth in the relevant tissue (plaque and vessel wall) and use pulses such that each pulse achieves a required thermal effect and with a repetition interval between pulses that is longer than the thermal diffusion period. This ensures that no thermal damage is induced on further located tissue, due to thermal diffusion in the tissue. For example, using a pulsed Er:Yag source at 2.9 micron would require light-energy emitting section 31 to emit a fluence level of around 20 – 35 mJ/cm<sup>2</sup> per pulse, and would heat a tissue volume with a depth of less than several microns. Heating the small volume of tissue combined with the pressure exerted by light-energy emitting section 31 on the same exact tissue volume facilitates creation of cracks and/or “cuts” or bond-weakening in the tissue, and therefore facilitate the dilatation of balloon body 2. Other various wavelengths, preferably in the range below 0.55 microns or above 1.5 microns are suitable for such heating of tissue. An alternative preferred waveform includes the emission of packages of very short pulses (each package of pulses includes several very short pulses), such that the duration of each package of pulses is shorter than the thermal diffusion period and the interval between two packages of pulses is larger than the thermal diffusion period. The thermal effect of the package of pulses would be equivalent to the thermal effect of a larger duration pulse. Such a package of pulses can be achieved by using one source or several sources emitting in parallel through the same output and being synchronized to sequentially emit pulses, such that the delay between the sequential emission of different sources satisfies the above conditions. Alternately still, under specific clinical conditions, the energy emitted by light-energy emitting section 31 for heating a radial confined volume of tissue may be in the form of longer light pulses or even continuous emission for short periods of time (up to several seconds) where the only constraint is ensuring that no thermal damage is induced to the tissue of the vessel wall. This might be implemented, for example in cases where at the beginning of inflation process light-energy emitting section 31 is at least several hundred of microns from blood vessel wall 150.

According to a second preferred option, the energy emitted by light-energy emitting section 31 is in the form of pulses with high fluence levels ensuring that most or all of the absorbed energy is converted into tissue vaporization and ejection of products. This operation mode will be further referenced as Collateral-Damage-Free Ablation (CDFA), and is a preferred mode of reducing restenosis due to lack of thermal damage to the tissue of the vessel wall. CDFA is preferably achieved with light pulses shorter than thermal diffusion period, where each pulse achieves the required effect, and with a repetition interval between the pulses that is longer than the thermal diffusion period. An alternative waveform includes the emission of packages of very short energetic pulses (each package of pulses includes several very short pulses), such that the duration of each package of pulses is shorter than the thermal diffusion period and the interval between two packages of pulses is larger than the thermal diffusion period. The effect of each package of pulses causes CDFA. As mentioned in the previous section as well, such a package of pulses can be achieved by using one source or several sources emitting in parallel through the same output and being synchronized to sequentially emit pulses, such that the delay between the sequential emission of different sources satisfies the above conditions. An additional private case of using such a waveform includes the usage of femtosecond lasers and femtosecond laser pulses. In this case, the effect is achieved by multiphoton absorption leading to ionization and optical breakdown of the tissue. Preferably still, CDFA is performed at wavelengths where the absorption coefficient of plaque is high (the penetration depth of the light energy is small), and ensures that only a very controlled and confined volume of tissue is affected. For example, using wavelengths in the UV band (below 0.32 microns) or in the IR (above 2.2 microns) ensures a small penetration depth per pulse (magnitudes of microns up to several tens of microns) and reduces the amount of energy required per pulse. For example, using an Er:Yag source at 2.9 micron would require light-energy emitting section 31 to emit a fluence level in the range of  $0.7\text{J}/\text{cm}^2$  to  $3.0\text{J}/\text{cm}^2$  (or above) per pulse. The selection of the wavelength can be based on choosing wavelengths that are strongly absorbed by most types of encountered tissue, such as UV (0.308 micron, for example) or IR (2.2 micron and above) or on choosing wavelengths that are highly absorbed by specific cromophores existing in the plaque or tissue to be dilated. For example, in tissue with a high enough content of blood it is possible to use light wavelengths that are highly absorbed by hemoglobin (wavelengths between 0.2 to 0.55 micron).

Optionally, in order to effectively use wavelengths that are sub-optimal in regular usage – i.e. – have a large penetration depth in tissue (small absorption coefficient) – an alternative method is to use a substance that when, for example, impregnated in basic balloon body 2 and released during the light interaction process increases the absorption coefficient of the tissue for the specific wavelength and decreases collateral damage. An optional substance is Hematoporphyrin (HPD) that is documented for increasing the absorption of plaque for specific light wavelengths. Alternative methods may even include oral Carotene that seems to be selectively retained in plaque or other substances being delivered prior or during the procedure through the balloon catheter or other percutaneous or no-percutaneous methods.

During the inflation of basic balloon body 2, the externally attached light-energy emitting section 31 pressures the tissue in the exact area that was first ablated/evaporated/bond-weakened by the effect of delivering radial confined light energy 105. Therefore, during the inflation process, externally attached light-energy emitting section 31 facilitates the splitting of the atherosclerotic plaque or thrombosis through a combined effect of energy delivery and mechanical effects.

A dilatation balloon catheter relying on the microscopic longitudinal opto-mechanical effect described above (and further disclosed in the detailed description) can overcome the difficulty of dilating rigid, elastic or diffusely diseased segments, and ensure a smooth dilatation process at lower pressure if matched by a proper selection of the balloon material and design and by the inflation rate.

Opto-mechanical designs may include the usage of a special bonding material between set of balloon externally attached optical fiber 3 and basic balloon body 2 along the external perimeter, or the addition of a basis 23 for supporting light energy emitting section 31 on basic balloon body 2. Radio-opaque markers 431, 432 enable to visualize by standard Fluoroscopy imaging the position of light-energy emitting section 31 with respect to blood vessel wall 150. Optional additional radio-opaque markers 433 may be used to delimit the position of the distal catheter member 41. Additional radio-opaque markers may be attached in order to delimit the segment of basic balloon body 2 according to current common practice.

According to a preferred geometry illustrated in Fig. 2a and 2b set of balloon externally attached optical fibers 3 includes four optical fibers that are equally deployed longitudinally on the perimeter of basic balloon body 2. Light-energy

emitting section 31 ends in a totally reflecting element 32 ensuring that light energy is delivered only in to required segment of blood vessel wall 150. Preferably, light-energy emitting section is coated on the side adjacent to basic balloon body 2 in order to increase the efficiency of radial light-energy emission towards the adjacent tissue. Set of balloon externally attached optical fibers 3 also include an optical fiber proximal section 33 that has a coating layer ensuring that no light energy is delivered by this proximal section to the adjacent anatomy. Preferably, set of balloon externally attached optical fibers 3 terminate in an optical fiber extension member 34 that continues after totally reflecting element 32. Optical fiber extension member 34 is not required to transmit light energy, and can be manufactured from any suitable material, preferably an elastic polymer or plastic material, and is optionally used only due to mechanical design considerations.

As illustrated in Fig. 2c one or more fiber bonding elastic elements 36 may be optionally used in order to ensure that set of balloon externally attached optical fibers 3 remains attached to basic balloon body 2 during the operation, and particularly that set of balloon externally attached optical fibers 3 and basic balloon body 2 re-wrap properly after being deflated.

During the endoluminal maneuvering of dilatation balloon catheter 1 through blood vessel wall 150 to a required anatomic position, basic balloon body 2 is totally deflated and set of balloon externally attached optical fibers 3 are fully deployed – see Fig. 2b – creating a flexible yet firm structure that can easily be passed through obstructing areas, such as areas where blood vessel wall 150 is partially occluded by severe atherosclerotic disease. Due to the material from which set of balloon externally attached optical fibers 3 are manufactured such maneuvering can in general be safely performed without modifying basic balloon body 2. The flexible nature of the light delivery means enables to manufacture virtually any commonly used length of therapy section thus overcoming length limitations that may be associated to usage of externally metal shape objects. Particularly, light energy-emitting section 31 can have a length of up to 10 cm.

The design of basic balloon body 2 and the selection of its material will take into account the existence and action of externally attached optical fibers 3. Preferably, basic balloon body will be manufactured from a semi-compliant material. This selection can enable the balloon to smoothly expand at a certain pressure level based on the temporal opto-mechanical effect created by light energy-emitting section

31 without being in danger of over-stretching or injuring vessel wall 150. An alternative design includes the usage of a non-compliant material for manufacturing basic balloon body 2.

Optionally, basic balloon body 2 may include folding wings 21 as illustrated in Fig. 3a, or may include cavity-deformation 45 in catheter body intra-balloon section 43. Folding wings 21 or cavity-deformations 45, if implemented, ensure that basic balloon body 2 contains at least partially light energy emitting section 31 while basic balloon body 2 is not inflated. This optional modification can improve maneuverability during the endoluminal manipulation of dilatation balloon catheter 1 to a required position, preventing to a maximum extent any damage to blood vessel wall 150 due to set of balloon externally attached optical fibers 3. Addition of folding wings 21 or cavity-deformations 45 is an extra-precaution mean that also facilitates the bonding of set of balloon light energy emitting section 31 to basic balloon body 2. Optionally, not illustrated, folding wings 45 constitute a separate chamber (set of chambers) being inflated/deflated through a separate lumen. In this case the chambers can be partially inflated while moving the dilatation balloon catheter 1 through the lumen and deflated at the beginning of the balloon inflation process. The inflatable chambers constitute an optional additional precaution mean during the transition of dilatation balloon catheter 1 through the vessel lumen.

Reference is now made to Fig. 3c, and Fig. 3d that present additional mechanical methods for improving the opto-mechanical effect of externally attached optical fibers 3. Fig. 3c illustrates the option of using a basis 23 for supporting light energy emitting section 31, where basis 23 are attached onto or embedded in basic balloon body 2. Basis 23 can be made of a variety of materials and can have various shapes and levels of elasticity ensuring that it does not obstruct the inflation/deflation process while providing additional support and strength to the balloon section below externally attached optical fibers 3. Still optional (not illustrated) light energy emitting section 31 has a special shape with a wider base in order to gain better support from basic balloon body 2. Fig. 3d illustrates the option of adding/shaping the optical fibers with a protrusions 38 matched to the section that emits radial light-energy and also pressures the adjacent tissue. Protrusion 38 is transparent to the radial emitted light energy and optionally can assist in focusing the radiated light. Additional options (not illustrated) include usage of special shape optical designs for the light energy emitting section 31, such as elliptic optical fibers, shaped to optimize the opto-mechanical

effects. As illustrated in figure in Fig. 3c light energy emitting section 31 is placed in a separate chamber. If implemented, the separate chamber is made from a material being transparent for the radial light energy emitted by light energy emitting section 31, and at the same time having properties substantially similar to the material of basic balloon body 2 in terms of smoothness. Optionally, the separate chambers are part of basic balloon body 2, and in this case light energy emitting section 31 can be considered as being embedded in basic balloon body 2.

In order to operate properly dilatation balloon catheter 1 and set of balloon externally attached optical fibers 3 it is necessary to ensure that light energy emitting section 31 is positioned on the non-tapered section of balloon body 2 regardless of the inflation level of balloon body 2, and that radio-opaque markers 431 and 432 indicate at all time the position of light energy emitting section 31. Reference is now made to Fig. 4a and Fig. 4b that illustrate mechanical designs ensuring the proper wrapping and re-wrapping of externally attached optical fibers 3. According to further aspects of the first preferred embodiment set of externally attached optical fibers 3 are routed through catheter body 4 and can be connected through a proximal optical connector 53 to light-source optical output member 101. Preferably, optical fibers 3 are routed inside catheter body 4. Alternately, optical fibers 3 are part of catheter body 4 or are routed externally .As illustrated in Fig. 4a optical fiber proximal section 33 has a spare segment enabling to inflate basic balloon body 2 while ensuring that light energy emitting section 31 maintains its position on basic balloon body 2 regardless of the inflation level of basic balloon body 2. The spare segment can be routed inside or outside catheter body intermediary section 42. Optionally, the spare segment can be routed through an elastic attachment member 37 such as flexible hoops attached to tube-like catheter body 4 or routed through a flexible conduit The “spare” section of optical fiber proximal section 33 together with the optional elastic attachment member 37 or other similar mechanical elements enables to inflate/deflate basic balloon body 2 while keeping set of balloon externally attached optical fibers 3 attached onto basic balloon body 2 and then re-wrapping them properly.

An alternative optical design is illustrated in Fig. 4b. Set of externally attached optical fibers 3 is connected to a light-energy guide system 5 that includes an intermediary optical guide member 51, a proximal optical connector 53 and a distal optical connector 52. Distal optical connector 52 connects optically between intermediary optical guide member 51 and optical fiber proximal section 33.

According to one preferred embodiment set of balloon externally attached optical fibers 3 is connected to distal optical connector 52 regardless of the condition of the balloon: inflated or not inflated. According to an alternative embodiment set of balloon externally attached optical fibers 3 is connected to distal optical connector 52 only when basic balloon body 2 is at least partially inflated.

According to still an alternative optical design (not-illustrated) set of balloon externally attached optical fibers 3 are branches from light-energy guide system 5 that consists of an optical fiber of larger core.

Various other mechanical designs based on having a spare segment of optical fiber proximal section 33 can be considered in order to ensure that light energy-emitting section 31 is positioned on the non-tapered section of balloon body 2 regardless of the inflation level of balloon body 2.

Reference is now made to Fig. 5a, 5b that illustrate the steps in using dilatation balloon catheter 1 for achieving an optimal therapeutic effect. As a first step, dilatation balloon catheter 1 is endoluminally maneuvered to position basic balloon body 2 in the area of interest, i.e. the stenosed vessel including the atherosclerotic lesion. As mentioned, in previous sections, dilatation balloon catheter 1 has a greater maneuverability due to its firm but flexible structure due to the usage of adjacent set of balloon externally attached optical fibers 3. Once basic balloon body 2 is in position, the second step includes the activation of light source 100 in order to achieve an optimal energy level. Light energy is delivered through light-source optical output member 101 (and optionally through light-energy guide system 5) to set of balloon externally attached optical fibers 3. Once light energy emitting section 31 emits light energy at a required level, the third step is to gradually inflate basic balloon body 2 by using a standard high-pressure balloon inflation device with pressure control. This gradual inflation of basic balloon body 2 brings light-energy emitting section 31 in contact with blood vessel wall 150 that may be covered by atherosclerotic plaque 151. Alternately, steps two and three above are interchanged and light energy is delivered from light-source 100 to externally attached optical fibers 3 only after basic balloon body 2 is inflated to bring light energy emitting section 31 in contact to vessel wall 150 or plaque 151.

Further on, it might be advantageous in certain clinical conditions to activate the emission through light energy emitting sections 31 only at the beginning of the inflation process until the dilatation process successfully begins. All the embodiments

described in the current invention enable switching off the emission from all/ or part of the light energy emitting sections 31 at any stage during or after the inflation process.

The design of light-energy emitting section 31, combined with a proper selection of the light source parameters (wavelength, intensity and waveform) ensures that radial confined light energy 105 has only a very short interaction depth with the adjacent tissue, where the interaction depth is defined as the depth where the energy delivered to the tissue creates a selected tissue removal / tissue vaporization / tissue heating and bond-weakening effect. For example, for specific vascular applications the selected parameters and design can ensure that the interaction depth of radial confined light-energy 105 in the tissue is less than 20-50 micrometers, and that tissue at a distance of more than 50 micrometers from the light-energy emitting section 31 is not damaged. i.e. no irreversible damage is induced on tissue cells. For specific applications it is possible to reduce the interaction depth to magnitude of several microns, for example by using an Er:Yag laser that emits light with wavelengths of 2.9 micron.

Additional optional therapy effects can be achieved by delivering radial light-energy after the successful inflation of basic balloon body 2 in order to create longitudinal microscopic thermal effects that can prevent generation of prolific hyperplasia and therefore acute restenosis following the PTA procedure, for example in order to weld the microscopic induced cuts. In this case, the intensity and waveform and/or wavelength of the delivered light energy will be changed during this final therapy stage in order to obtain the required effect

Reducing the required dilatation pressure during the inflation process is of high importance in reducing restenosis effects. In order to achieve this goal it is necessary to select properly the material from which basic balloon body 2 is manufactured, and also to adjust the dilatation rate of basic balloon body 2 to the opto-mechanical effect achieved by light-energy emitting section 31. As described in previous sections the material from which basic balloon body 2 is manufactured and its shape are designed to benefit from the activation of light-energy emitting section 31. Preferably, balloon body 2 is manufactured from semi-compliant materials, or from a mix of layers that ensures semi-compliant properties. This ensures that at a given lower pressure basic balloon body 2 is capable of expanding and dilating the plaque assisted by the opto-mechanical effects induced in the plaque by light-energy

emitting section 31, while having a strong texture capable of supporting the mechanical pressure exerted by light-energy emitting section 31, and avoiding the risk of over-stretching or injuring vessel wall 150. According to preferred method of operation, the inflation rate is matched to the size and to the material of basic balloon body 2 and the pressure in basic balloon body 2 is not increased as long as the inflation rate matches the expected "cracking rate" created by the opto-mechanical effects of light-energy emitting section 31. Proper matching of the material and the design of basic balloon body 2 in combination with a matched inflation rate enable dilating the stenotic lesion at significantly lower pressures than regular dilatation balloons. According to a preferred design dilatation balloon catheter 1 is designed to dilate stenotic lesions when exerting a pressure between 2-5 atmospheres. According to alternate implementations balloon body 2 is manufactured from low-compliant or non-compliant materials, or from a mix of layers that ensures low-compliance or non-compliance properties. Optionally still, the material from which basic balloon body 2 is manufactured has a pressure range where it acts as a semi-compliant balloon and a pressure range where it acts as a low-compliant or non-compliant balloon, in order to ensure that there is a pressure range where the balloon inflation can benefit from the described opto-mechanical or thermo-mechanical effects induced by the radiating means, and at the same time there is no danger of over-stretching or inducing unwanted thermal or other damage to the vessel wall.

Several methods for adjusting the dilatation rate to the opto-mechanical effect are further described. According to a first preferred method and apparatus a control unit 110 automatically measures and correlates between the pressure in the balloon, and the size of the balloon (diameter, etc) as a function of time. According to an alternative semi-automatic method, control unit 110 indicates to the user the inflation rate vs. the expected rate and the user decides whether to increase the pressure in the balloon 2. According to still further alternative methods the user knows the expected inflation rate as a specification of the system and gradually increases accordingly the pressure in the balloon 2. The value of the expected inflation rate at a certain pressure might be dependent on the type of lesion and additional parameters that are automatically detected or manually indicated (such as type of vessel, level of calcification, etc).

The pressure in basic balloon 2 is induced and measured by existing methods (all the inflation systems currently commonly used to inflate dilatation balloon

catheters accurately indicate the pressure in the balloon) or by various alternative methods readily available for the skilled in the art. The shape/diameter of balloon body 2 can be measured by various methods and apparatus as further described. According to a first method and apparatus the shape of balloon 2 is measured by using the optical fibers themselves or additional optical fibers – for example by methods used by the Measurand company to measure shape. According to alternative method the diameter of basic balloon body 2 is measured by elasto-mechanical means. According to still alternate methods the shape/diameter of basic balloon body 2 is measured by imaging balloon 2 by various imaging modalities, such as endoluminal imaging modalities (IVUS, optical imaging, thermal imaging, intraluminal MR imaging, etc) or extraluminal imaging modalities: X-Ray images produced by angio systems or MR-angio images during the inflation of balloon 2.

According to alternative methods the dilatation rate is updated based only on time considerations. According to a first preferred method and apparatus control unit 110 automatically increases the pressure in the balloon to a certain level based on time considerations that are made according to the expected effect of light-energy emitting section 31. According to alternative methods, based on time measurement control unit 110 indicates to the user that it should increase the pressure by a certain amount.

According to still further options the user gradually increases the pressure in the balloon according to known values provided in accordance to the performance of the system. The value of time period before increasing the pressure in the balloon might be dependent on the type of lesion and additional parameters that are automatically or manually indicated (such as type of vessel, level of calcification, etc).

According to a still alternative method, the user can start and stop the delivery of light-energy through light-energy emitting section 31 according to the conditions encountered during the intervention. Moreover, control unit 110 can automatically cease the emission from all/part of the light delivery elements when the inflation level/pressure has received a certain level in order to prevent unwanted damage to healthy tissue and to the vessel wall.

Optionally, the light energy delivery process can be repeated several times during the inflation to minimize risks and particularly in cases of severe atheromatosis or heavily calcified atherosclerotic plaque. In severe cases, if required, basic balloon body can be re-inflated and delivery of radial confined light energy can be repeated to a required lumen segment. Still optionally, rotation of basic balloon body 2 in order to

create multiple longitudinal opto-mechanical microscopic cuts or tissue "cracks" can also be performed if clinically required. Still optionally, different waveforms and energy levels can be employed at different stages of the process in order to achieve an optimal clinical result. Still optionally, in cases where well organized plaque or heavy calcification obstructs the inflation of basic balloon body 2, delivery of light energy can be performed in different forms (wavelength/level of energy/duration of pulse) during the inflation in order to facilitate the recanalization process, and minimize the risk of complications.

According to an optional alternative design – not illustrated - basic balloon body 2 has a "dog bone" shape that when inflated seal the area to be treated. The "dog bone" shape can also be achieved by using three separate balloons where the 1<sup>st</sup> and the third are inflated at the beginning of the procedure in order to seal the area to be dilated and the 2<sup>nd</sup> (middle) balloon including the a set of balloon externally attached optical fibers 3 is used for a smooth dilatation of the stenotic area as described through out this document. Still optionally, saline or other biocompatible substance that transmits the light wavelength is used to flush (constantly or periodically) light energy-emitting section 31 in order to ensure that no residual blood or tissue parts are gathering on the emitting section. Basic balloon body 2 can have alternative shapes that can be useful for specific clinical applications.

Still, an additional optional modification to the dilatation balloon catheters 1 described in this invention may include the usage of a multi-lumen dilatation balloon catheter 1 where at least one lumen is used for allowing blood to profuse during the entire dilatation process.

Reference is now made to Fig. 5c and Fig. 5d that illustrate a method for the activation of a dilatation balloon catheter 1 with externally attached optical means. Blood vessel lumen presents an asymmetric/eccentric stenotic region as illustrated. In this case, it is optimal to emit light-energy only through light energy emitting sections 31 that are facing the larger volume stenotic plaque 151. Such a selective activation has clinical advantages and prevents unnecessary damage to blood vessel wall 150.

The selective activation can be performed for all the embodiments described in the current invention where there is a separate/or at least partially separate channel for each/or for sub-groups of externally attached light delivery elements.

Several methods can be used in order to assess the asymmetry in the stenotic plaque. These methods include but are not limited to IVUS imaging, endoluminal

imaging modalities based on MR imaging, endoluminal imaging modalities based on optical reflection or other optical effects, external imaging modalities such as MRI.

According to one preferred embodiment light energy emitting sections 31 or other optical elements are used for determining the nature of the tissue adjacent to them. This can be performed by various infrared (IR) spectroscopic methods such as attenuated total reflectance (ATR) Fourier Transform IR (FTIR). This type of IR spectroscopy which is based on measuring the absorption of totally internally reflected IR beam when the beam becomes into contact with tissue, and therefore is most adequate for determining the type of tissue adjacent to light energy emitting sections 31. It is even possible to automatically control the selective/non-selective emission based on the real-time spectroscopic measurements produced before, during and after the inflation process.

The clinical effect on blood vessel wall 150 and atherosclerotic plaque 151 is illustrated in Fig. 6a and 6b. The illustrated cross-section of blood vessel wall 150 clearly shows the expected cuts of atherosclerotic plaque 151 and intima layer 152 that are the result of . the combined mechanical and radial light energy delivery effect of externally attached optical fibers 3.

To summarize, a dilatation balloon catheter with externally attached optical fibers 3 as described in the previous embodiments and based on the clinical workflow and method described in connection to it provides several important clinical advantages:

- Overcome the dilatation of rigid, elastic or diffusely diseased segments;
- Significantly lower chances for hyperplasia and prevent abrupt closure of the dilated segment due to the microscopic opto-mechanical cuts and the matched balloon inflation rate resulting in lower inflation pressure.
- Significantly lower the incidence of restenosis after successful expansion of the blood vessel lumen.

As already mentioned in order to achieve the optimal clinical effect it is important to use an extremely localized light-energy delivery and thermal confinement that does not induce spread thermal damage to the vessel wall. Fig. 7a is illustrating the fading energy profile of an evanescent light wave. As illustrated in Fig. 7a, if the delivery of light-energy to the tissue is made in the form of an evanescent wave, the significant energy delivery in tissue is confined to a very small volume adjacent to light-energy emitting section 31. This volume of adjacent tissue can be as

small as magnitudes of several microns or less. If required, a larger treatment volume can be achieved by changing wavelength, duration or energy level of the delivered light energy. The main problem with the usage of evanescent wave methods is that the efficiency is low, and that it is highly dependent on having a proper angle between the light propagation direction and the interface between the optical fiber and the tissue, which can result in a poor uniformity along the length of light energy emitting section 31, and thus in lack of repeatability and even to unwanted tissue thermal damage. Having low efficiency in the light-delivery elements 31 increases the light-energy level required for achieving the desired therapeutic effect (i.e. larger light source, larger light-delivery elements with a larger damage threshold and causes unwanted heat and ultimately thermal collateral damage that could eventually lead to increased levels of restenosis.

The materials from which (the light energy delivery means) set of balloon externally attached optical fibers 3 and optional light-energy guide system 5 are manufactured and their optical design are selected according to the selected light-source and wavelength. There are several radial light-energy delivery methods and optical designs of light-energy emitting section 31 capable of emitting radial light-energy with a high efficiency rate and capable of achieving the required energy confinement without inducing collateral damage effects. These methods and designs ensure uniform light-energy delivery along the radial light-energy emitting section 31, which is a critical feature in designing a robust and repeatable apparatus.

According to a first preferred method and apparatus, illustrated in Fig. 7b, the cladding of radial light-energy emitting section 31 is removed on the side facing the tissue, and a thin layer of higher refractive index material 311, for example optical epoxy is used in order to achieve a uniform scattering effect over the entire radial light-energy emitting section 31. The thin layer of higher refractive index should preferably be made from a mixture of at least two materials with different refractive indexes (one significantly different from the other) in order to couple out the energy outside the optical fiber. In order to achieve uniform amount of energy delivery along radial light-energy emitting section 31 the output-coupling factor should increase along its length. This can be achieved in the case of using the thin coating layer of higher refractive index by changing the thickness of the coating layer 311 or the mixture percentage along the length of the fiber. Preferably, the cladding on the side attached to basic balloon body 2 is left intact in order to ensure maximal reflectance

towards the tissue. Optionally, a thin metal layer ensuring an even higher reflectance coats the fiber side attached to basic balloon body 2. The design illustrated in Fig. 7b ensures a high level of longitudinal and angular uniformity of the emitted light energy – as illustrated in Fig. 7c – that is imperative for achieving repeatable results.

Alternative designs and apparatus for radial light-energy emitting section 31, include design of a special dispersive fiber core, for example by usage of specially designed hollow light-guides or all-dielectric fibers consisting of a periodic array of air holes in silica (similar in concept although opposite in result to designs of photonic crystal fibers). Still alternative optical designs (not illustrated) for emitting a radial confined light-energy are based on the usage of an optical fiber with a tapered thinner cross-section (core and/or cladding) for the radial light-energy emitting section 31 causing dispersion of a light wave in this thinner section. According to still alternative techniques radial light-energy emitting section 31 has preferably a roughened surface on the side facing/in contact to the tissue. According to still alternative designs – not illustrated - radial light-energy emitting section 31 consists of a group of internal reflecting (or partially reflecting) surfaces that direct laterally the light energy towards the tissue. If implemented group of internal reflecting surfaces would have increasing size towards the distal part of the radial emitting section 31 in order to ensure longitudinal uniform illumination. According to still alternative designs – not illustrated - radial light-energy emitting section 31 consists of a group of internal optical refracting surfaces or elements that direct laterally the light energy towards the tissue. If implemented the optical refracting surfaces or elements would ensure the longitudinal uniformity required.

It is particularly advantageous to limit the area through which the radial emission occurs in order to reduce the collateral damage and in order to reduce the required amount of energy required from the laser source. Given that the required fluence for achieving a required effect is Fluence\_Threshold (J/cm<sup>2</sup>), the total required energy is:

$$\text{Total_Energy} = \text{Fluence_Threshold(J/cm}^2\text{)} * \text{Length_Arc(cm)} * \text{Length(cm)}$$

where Length(cm) is the length of light energy-emitting section 31 and Length\_Arc(cm) is the length of the arc used for radial emission. In order to reduce the required energy levels it is possible to decrease the arc through which the radial

emission is performed. For example, when using optical fibers with a diameter of 80 microns it is possible to limit the radial emitting section to an arc of less than 25 microns, design that requires only 1/5 of the energy required to emit through the entire 180° of the upper arc of light-energy emitting section 31. Optionally, (not-illustrated) radial light-energy emitting section 31 consists of longitudinally interlaced sections that emit radial light-energy and sections that do not emit radial light-energy. Given that the sections not emitting are small enough the mix is capable of achieving the required effect while reducing the required total energy. Such a design can be achieved for example, by using a group of internal reflecting (or partially reflecting) surfaces or a group of optical refracting surfaces or elements as described in the previous paragraph.

Reference is now being made to Fig. 8a, Fig. 8b. and Fig. 8c. The endoluminal maneuvering of basic balloon body 2 to a desired position may be implemented in various ways. In principle, the maneuvering method can be based on any of the existing method such as: classical “Over-the-Wire” method, or “MonoRail” method. For example, as illustrated in Fig. 8a, the maneuvering and transport system can be a regular “MonoRail” angio mechanism including a guide-wire 6 that is passed through a bore 46 in the distal part of catheter body intermediary section 42, passes next to the distal part of inflation system 20 and continues through a bore in distal catheter member 41. An alternative mechanism is the “over-the-wire” method illustrated in Fig. 8b. In this case guide-wire 6 is inserted through a guide-wire insertion connector 47 connected to the proximal tube-like catheter lumen. (Fig. 8b also illustrates the usage of optional intermediary optical guide member 51 and distal optical connector 52).

An alternative design could be the usage of a “MiniRail” (MiniRail is a trademark of X-Technologies Ltd.) as illustrated in Fig. 8c.

Reference is now being made to Fig. 9. In this preferred embodiment light source 100 is a solid-state laser source based on an Nd:Yag laser with an Optical Parametric Oscillator (OPO) module capable of producing laser energy in the form of continuous or controlled pulses with emitted wavelengths in the range between 0.2 microns to 3.5 microns. Light source 100 is capable of emitting light energy at one or more specific predefined wavelengths. Optionally, several wavelengths can be emitted in parallel by using multiple sources or by using beam-splitting optics from a single source. Various other light sources capable of emitting a single wavelength or a set of wavelengths can be alternatively used, such as Er:Yag, Ho:Yag, doubled

Nd:Yag, excimer lasers such as (XeF), other diode-lasers, diode-pumped lasers or fiber-lasers with or without additional mixing or doubling or OPO modules. Light source 100 can be based on a single light source or several light-sources used in parallel or sequentially.

As mentioned in previous paragraphs, light source 100 emits light at a wavelength for which the plaque or other relevant tissue has a high absorption coefficient. Still preferably, and as previously stated, light energy is emitted by light-source 100 in the form of pulses with duration of less than the thermal diffusion rate (of the tissue to be treated) and with a repetition interval between the pulses that is longer than the thermal diffusion rate of the relevant tissue. An alternative waveform includes the emission of packages of very short energetic pulses (each package of pulse includes several very short pulses), such that the duration of each package of pulses is shorter than the thermal diffusion period and the interval between two packages of pulses is larger than the thermal diffusion period. Such a waveform can be achieved by using a single source or several synchronized sources with a common output and used sequentially. A private case of such a waveform includes usage of femtosecond lasers and femtosecond laser pulses. The effect is achieved in this case by multiphoton absorption that leads to ionization and optical breakdown of the tissue.

Light source 100 may include a power supply unit or battery 102 that would ensure stand-alone operation of light source 100 without the need to connect it to power during the intervention. Light source 100 may or may not be disposable after one or more interventions. Light source 100 may be of moderate size, enabling to be placed in the working area without obstructing the user or even to be held by the user during the intervention. Alternately, light source 100 may be connected to an external power source/power net during the intervention.

According to still further aspects of the current invention the operation of light-source 100 is controlled by means of a control unit 110. Control unit 110 can include the user interface 111 an inflation correlating sub-unit 112 for correlating between the inflation rate of basic balloon body 2 and the opto-mechanical effect achieved by set of balloon externally attached optical fibers 3. Inflation correlating sub-unit 112 can be based on sensors and algorithms as above described. Control unit 110 also includes a built-in-test sub-unit 113 comprising apparatus and algorithms for detecting failures in the light-source 100 or externally attached optical fibers 3. This is

particularly important in cases where the optical fibers 3 were involuntarily damaged. In cases of failure or damage of light-source 100 and/or externally attached optical fibers 3, built-in-test sub-unit 113 issues an alert to the user through user interface 111 and/or automatically stops the operation of light-source 100.

In order to reduce the amount of peak and average energy required from light-source 100 it is optionally possible to multiplex the light emission between externally attached optical fibers 3 by regular optical means. This is particularly useful when employing high energy levels required for Collateral-Damage-Free Ablation (CDFA). For example, when using four externally attached optical fibers 3 it is possible by multiplexing two fibers at a time to reduce the peak power by half.

Light source 100 can be designed to support several therapeutic actions:

- Assist a smooth dilatation of a stenotic lesion by means of radial emitted light-energy through light energy emitting section 31.
- Enable tissue welding at the end of the dilatation process.
- Activate a Photodynamic Therapy (PDT) process after or during the dilatation process.

The transfer between the modalities can be done by the user by pressing a functional button or semi-automatically by control unit 110 in specific procedures – such as PTCA – based on time or pressure/size considerations.

Control unit 110 preferably recognizes automatically the length of light energy emitting section 31 and /or size of balloon basic body 2, for example by including an encoded element in proximal optical connector 53, where the code indicates the type of balloon and its working length. For example, for a 3cm length the required overall power will be twice the overall power for a 1.5cm length. Alternately, the user can indicate the relevant parameters (type of balloon, etc) through user interface 111, and control unit 110 will adjust accordingly the energy levels and waveforms or even optionally the wavelength. Similar automatic methods can be used if required in order to switch-on/switch-off or regulate the light intensity level according to the pressure level/inflation diameter of basic balloon body 2.

Optionally, control unit 110 is able to adjust waveform/intensity or even wavelength according to the type of tissue adjacent to the radial light-energy emitting section 31. Recognition of the type of tissue can be done by means of medical imaging devices such as X-Ray, Doppler Ultrasound, CT-Angiography, MR-Angiography, IVUS or other suitable imaging devices. Optionally, light-delivery

elements 3 or additional optical elements enable to establish the type of tissue by spectroscopic methods. Still optional control unit 110 and user interface 111 enable the user to manually indicate the type of vessel (for example, coronary, peripheral, etc) and type of tissue (for example, yellow plaque, calcified, etc), and control unit 110 will adjust waveform/intensity or even wavelength accordingly.

According to further variations, the entire dilatation balloon catheter 1, light-energy guide system 5 and light-source 100 are MR compatible and can be used inside an MRI suite, for performing intraluminal interventions with the assistance of MR imaging. Particularly dilatation balloon catheter 1 and light-energy guide system 5 can be used inside an open or closed MR system. Radio-opaque markers 431, 432 and 433 would be replaced in such an application by MRI visible markers. For such an intervention, specific MR protocols can be utilized for monitoring the temperature around the “light-energy” blades.

Reference is now being made to Fig. 10a. According to the embodiment, illustrated in Fig. 1 and Fig. 4a and as detailed above, optical fiber proximal section 33 passes through bores in catheter wall intermediary section 42. Fig. 10a illustrates an alternative design and apparatus for routing externally attached optical fibers 3. As illustrated in Fig. 10a set of balloon externally attached optical fibers 3 are routed through catheter wall intermediary section 42 and exit tube-like catheter wall 4 through distal catheter member 41. In this alternative embodiment, intermediary optical guide-member 51, if used, - see Fig. 10b - is continued till distal catheter member 41 that includes distal optical connector 52. Optical fiber extension member 34, can optionally be used due to mechanical considerations, and is manufactured from an elastic material. Optical fiber extension member 34, if used, can be externally connected to catheter wall intermediary section 42. Preferably, optical fiber proximal section 33 has a “spare” part that can glide through distal catheter member 41 while maintaining light-energy transmission capability, and enables proper wrapping and re-wrapping during inflation/deflation of basic balloon body 2.

Reference is now made to Fig. 10c. Set of optical fibers 3 are connected in a cooperative structure by means of several elastic fiber bonding elements 36. Optical fibers 3 have at their distal end a light energy emitting section 31 ending in a totally reflecting element 32 and an optional optical fiber extension member 34. Optionally, optical fiber extension members 34 may be attached together in a optical fiber-distal connecting member 35 that has the structure and properties of a regular guide-wire

tip. Dilatation balloon catheter 1 has a basic balloon body 2. The elasticity of elastic fiber bonding elements 36 (one or more) enables to slide the cooperative structure built from set of optical fibers 3 onto dilatation balloon catheter 1, such that light energy emitting section 31 is positioned and firmly attached onto basic balloon body 2, and particularly on the non-tapered part of basic balloon body 2. Once attached onto basic balloon body 2 it is possible to operate dilatation balloon catheter 1 and externally attached set of optical fibers 3 as described in the embodiments illustrated in Fig. 1 to 10.

Reference is now made to Fig. 10d that illustrates a dilatation balloon catheter 1 that includes a set of externally attached optical fibers 3 and also one or more internal forward emitting light-delivery elements 120. The functionality of externally attached optical fibers 3 is as described in the embodiments illustrated in Fig. 1 to 13. The internal light-delivery elements 120 have the role to assist in crossing dilatation balloon catheter 1 through partial occlusions or chronic total occlusions. According to a preferred embodiment light-delivery elements are a fiber bundle being connected at their proximal side to light-source 100 and having a distal end 121 capable of emitting forward light-energy. Distal end 121 is passed through distal catheter member 41. Light-source 100 has an output optical design enabling the user to select whether to transmit use the forward-emitting light-delivery elements 120 for crossing occlusions and between using externally attached optical fibers 3 for dilating the occlusion (once the occlusion was first crossed).

The usage of dilatation balloon catheter 1, and in general the delivery of radial confined light energy can be conducted regardless of whether a stent is already placed in the area to be treated without danger of mechanical obstruction or other interference. Particularly, dilatation balloon catheter 1 externally attached optical fibers 3 can be used for treating restenosis, i.e. dilating stenosis that occur in a stented vessel segment. Optionally, light-source 100 and externally attached optical fibers 3 are capable of emitting light-energy at wavelength and intensities capable of cutting the stent.

Reference is now made to Fig. 10e. Dilatation balloon catheter 1 including externally attached optical fibers 3 is used for delivering a stent 170 to treat a stenosed lesion. Primary stenting is currently limited by the risk of the stent being stuck in cases of unsuccessful dilatation. This requires as a first step to dilate the stenosis by using dilatation balloon catheter and only after the successful dilatation to bring the

stent and position it in order to secure the lesion. Based on the capability of dilating hard to expand lesions dilatation balloon catheter 1 with externally attached optical fibers 3 can be used as a delivery system for primary stenting diminishing the risk of an unsuccessful dilatation. According to a preferred option stent 170 is a regular stent and the radial emitted light-energy due to the selected wavelength and intensity is not causing any damage to the stent, and it is not altering its properties. This is due to the fact that, for example short light pulses with energy levels capable of heating or ablating adjacent tissue will not affect stent 170. According to one possible design, the attachment points of stent 170 to externally attached optical fibers 3 are thermally shielded avoiding thermal diffusivity due to thermal conductivity of stent 170. According to an alternate design, stent 170 has a special structure ensuring its bonding to basic balloon body 2 during its transition. According to still additional options, stent 170 is attached to basic balloon body 2 by bonding elements that release stent 170 from basic balloon body 2 after emitting light-energy through externally attached optical fibers 3.

Reference is now being made to Fig. 11a, Fig 12a and Fig 12b illustrating a second embodiment of the current invention. This embodiment describes apparatus and methods for locally activation of light sensitive drugs by means of light-delivery means attached to a dilatation balloon catheter. Set of balloon externally attached optical fibers 3 is connected to light source 100 as described in the embodiments illustrated in Fig 1 to 10. In order to achieve the required interventional and therapeutic effect set of balloon externally attached optical fibers 3 have a light-energy emitting section 31 capable of emitting radial light energy 105 preferably in the form of a diffused light wave as further described. Radial light energy 105 is delivered to blood vessel wall 150 directly through the contact surface of the optical fibers and/or through basic balloon body 2 that can be made transparent to the specific wavelength(s) emitted by light-energy emitting section 31. Basic balloon body 2 can also have areas that are opaque to the specific wavelength(s) emitted by light-energy emitting section 31 in order to ensure that the activation of the drug is prevented outside the required area. Optionally, as illustrated in Fig. 2b, basic balloon body 2 may include an external membrane 22 over the light-energy emitting section 31. Usage of optional external membrane 22 can further spread the light-energy emitted by light-energy emitting section 31.

Reference is now made to Fig. 13a, 13b that illustrate the steps in using dilatation balloon catheter 1 illustrated in Fig 11 and as described in the second embodiment for achieving an optimal therapeutic effect. As a first step, basic balloon body 2 is maneuvered through the vessel and positioned in the area of interest, for example the stenosed vessel segment including the atherosclerotic lesion. Once basic balloon body 2 is in position, the second step includes the activation of light source 100 in order to achieve an optimal energy level. Light energy is delivered through light energy emitting section 31. The third step is to gradually inflate basic balloon body 2 by using a standard high-pressure balloon inflation device with pressure control. This gradual inflation of basic balloon body 2 brings set of balloon externally attached optical fibers 3 in contact with blood vessel wall 150 that may be covered by atherosclerotic plaque 151. The light energy emitted by set of balloon externally attached optical fibers 3 activates the light sensitive drug. The special structure of light-energy emitting section 31 ensures delivery of radial light energy 105 to blood vessel wall 150 and atherosclerotic plaque 151. Alternately, steps two and three are interchanged and light energy is delivered through light energy emitting section 31 only after basic balloon body 2 is initially inflated. Alternately, light-energy emitting section 31 can emit through out the dilatation process activating the light sensitive drug during and after the dilatation process.

The advantage of using balloon externally attached optical fibers 3 emitting light energy for activation of light sensitive drugs in vascular applications and similar clinical applications such as treatment of stenoses in the biliary system the urinary system or gastrointestinal system, resides in the following aspects that are advantageous for such interventions:

- The area where the drug is activated is easily controlled.
- Activation of light sensitive drugs is easier and safer to perform;
- The same dilatation balloon can be used for multiple therapy tasks including controlled inflation integrated with microscopic light-energy opto-mechanical cuts as described in the first preferred embodiment of the current invention

As above described the same dilatation balloon catheter 1 with a set of externally attached optical fibers 3 can be used for creating microscopic longitudinal cuts through the opto-mechanical effect created by light energy emitting section 31,

and can also be used for activating photosensitive drugs. . In order to achieve optimal clinical results, two different workflows can be implemented.

According to a first preferred method and apparatus the wavelength used for creating the microscopic light-energy opto-mechanical cuts is different than the wavelength used for activating the light sensitive drug. In this case the balloon is first inflated and only then the drug is activated.

According to a second method and apparatus the same wavelength is used for creating the microscopic light-energy opto-mechanical cuts and for activating the light sensitive drug. In this case the drug is activated during or after the inflation process, according to the drug delivery method.

Taking, for example, a light-source capable of generating wavelength(s) of 0.308 microns and also of 1.053 microns, the following methodology can be implemented (similar methodologies can be implemented at other wavelengths). After positioning the dilatation balloon in the stenotic area to be re-canalized the light source is activated at 308 microns. At this wavelength for most types of tissue the absorption coefficient is high, (i.e. the penetration depth is very small), and the radial confined light-energy emitted by externally attached light energy emitting sections 31 combined with their pressure create microscopic longitudinal cuts or "cracks" in the atherosclerotic plaque 151. After the successful dilatation of the stenotic lesion light-source 100 emits low intensity light-energy at 1.053 microns in order to stimulate drug delivery and/or drug activation that is useful for example in preventing restenosis. Optionally, the emission at 1.053 microns can be activated in parallel to the dilatation process.

The light activated drug can be delivered to the required blood vessel section by various methods. According to a first preferred method, the light activated drugs are delivered by the balloon catheter itself. Various schemes are readily available for such drug delivery, such as Microporous Balloon manufactured by Cordis, the Dispatch Delivery catheter by Scimed, Infusion Sleeve by LocalMed Inc., Hydrogel balloon by Boston Scientific, etc. Each of the above mentioned balloon catheters can be used in connection to the current invention with the proper adjustments necessary for adding the external light delivery means attached to basic balloon body 2.

According to an alternative method the light activated drugs are delivered by injections in the area of interest, or unselectively through out the entire blood vessel wall.

Various drugs/agents can be used in connection to PDT. The group of relevant drugs/agents includes, but it is not limited to streptokinase, urokinase, heparin, enoxaparine, etc.

Reference is now made to Fig. 11b illustrating an alternative optical design capable of facilitating dual therapy effects to dilatation balloon catheter 1. Dilatation balloon catheter 1 includes a set of externally attached optical fibers 3 and also one or more internal radial emitting light-delivery elements 130. The functionality of externally attached optical fibers 3 is as described in the embodiments illustrated in Fig. 1 to 10. The internal radial emitting optical element 130 has the role of stimulating drug delivery and/or drug activation. Light-source 100 and light-source optical output member 101 enable the user to select between using externally attached optical fibers 3 for dilating the occlusion (once the occlusion was first crossed) and between using internal radial emitting optical element 130 for photodynamic therapy. Optionally, light-source 100 and light-source optical output member 101 are capable of supporting parallel emission through both externally attached optical fibers 3 and through internal radial emitting optical element 130 at the same wavelength or at separate wavelengths as described in previous sections. Still optionally, light-source 100 and light-source optical output member 101 are capable of supporting by multiplexing or in parallel emission through forward emitting light-delivery elements 120 (as illustrated in Fig. 10d and described in previous sections), emission through externally attached optical fibers 3 for dilating the occlusion (once the occlusion was first crossed) and emission through internal radial emitting optical element 130 for photodynamic therapy.

Reference is now made to FIG.14, Fig 15a and Fig 15b that illustrate an alternative design and apparatus for a dilatation balloon catheter capable of dilating stenotic vessels at lower pressures with minimal induced damage to the vessel wall. With respect to Fig 15a, a dilatation balloon catheter 11 includes a light energy guide system 5 with an optical inter-balloon element 55 capable of emitting radial light-energy. The distal part of optical inter-balloon element 55 ends in totally reflecting element 56. The optical design described in connection to light energy emitting section 31 is preferably used for optical inter-balloon element 55 in order to ensure uniformity and high efficiency. The diameter of optical inter-balloon element 55 is preferably between 200-300 microns capable of transmitting higher energy levels.

Alternate diameters can be used according to the size of the vessel and the clinical application.

According to a first preferred apparatus, a set of externally attached optical elements 200 are attached or embedded in basic balloon body 2 and are capable of transmitting radial confined light-energy 105 from optical inter-balloon element 55 to blood vessel wall 150 and stenotic plaque 151. Externally attached optical elements 200 have a longitudinal shape spanning the entire balloon section (the non-tapered) section used for dilating the stenotic vessel, and are preferably equally spread on the perimeter of the basic balloon body 2. Externally attached optical elements 200 can be designed to act as a light-focusing element or can be designed to be only an optical window for transferring the light-energy to the adjacent tissue. Externally attached optical elements 200 have a firm, yet flexible structure ensuring that during the inflation of basic balloon body 2 they exert an adequate pressure on the heated /ablated /evaporated /bond-weakened tissue adjacent to them. The structure of externally attached optical elements 200 increases the endoluminal maneuverability of dilatation balloon catheter 1.

Additionally, optional intra-balloon focusing elements 202 can be used to focus the radial light energy emitted by optical inter-balloon element 55 on externally attached optical elements 200 and/or a confined tissue volume adjacent to them. According to further aspects of the current invention intra-balloon focusing elements 202 expand or change their angle as the balloon expands, in order to ensure a fixed distance from basic balloon body 2 and externally attached optical elements 200, and to ensure that radial confined light energy is delivered to tissue adjacent to attached light focusing elements 200 regardless of the inflation level of basic balloon body 2. Other optical methods for focusing the radial emission through externally attached optical elements 200 may include angulations of intra-balloon focusing elements 202 according to the inflation of basic balloon body 2. Optionally, externally attached optical elements 200 and/or intra-balloon focusing elements 202 are part of basic balloon body 2. Externally attached optical elements 200 and intra-balloon focusing element 202 are manufactured from materials and have an optical design in accordance to the selected wavelength and intensity.

According to alternate optical design, optical inter-balloon element 55 has a special optical design ensuring that its radial emission is focused on externally attached optical elements 200. According to further aspects of the current invention,

basic balloon body 2 can be coated in certain areas to reflect the radial light-energy emitted by inter-balloon section 54 and provide additional light -focusing on the externally attached optical element 200. The focusing effect may also be achieved by varying the width and materials of basic balloon body 2 in certain areas.

Fig. 15b illustrates an alternative apparatus where light energy guide system 5 and optical guide inter-balloon section 55 includes several optical fibers each emitting radial light-energy. Optionally, these optical fibers can optionally expand as basic balloon body 2 is inflated maintaining a fixed distance from externally attached optical elements 200 regardless of the inflation level of basic balloon body 2.

During a Percutaneous Transluminal Angioplasty procedure dilatation balloon catheter 11 is connected to a light-source 100 and operated similarly to the operation of dilatation balloon catheter 1 described in above embodiments that are illustrated in Fig. 1 to 13. Externally attached optical elements 200, facilitate a smooth inflation process due to an optimal combination of optical and mechanical effects that create longitudinal microscopic cuts or bond-weaken segments in the stenotic plaque 151. Similar to the described functionality of dilatation balloon catheter 1 and light energy emitting section 31, externally attached optical elements 200 deliver confined longitudinally uniform light-energy to a microscopic volume of adjacent tissue and at the same time due to its firm structure and shape exerts mechanical pressure on the same volume of adjacent tissue. Once a required inflation level is achieved the light-delivery is stopped in order to ensure that no unwanted damage is induced on vessel wall 150.

Selective activation can be implemented when using externally attached optical elements 200 pending that optical guide inter-balloon section 55 is designed to enable selecting the emitting section, for example as illustrated in Fig. 15b.

Optical inter-balloon element 55 and externally attached optical elements 200 can also be used for activating light sensitive drugs as described in previous embodiments. In this case, according to a first preferred implementation the same wavelength is used for creating the microscopic opto-mechanical cuts and also for the drug activation. According to an alternate implementation one single/set of wavelengths is used for creating the microscopic opto-mechanical cuts and another single/set of wavelengths is used for the drug activation. In the later case basic balloon body 2 can be coated in certain areas as to reflect the light-energy at the

wavelength(s) used for creating the microscopic cuts and at the same time being transparent for the wavelength(s) used for drug activation.

Optionally, light-source 100 and light-source optical output member 101 are capable of supporting by multiplexing or in parallel emission through forward emitting light-delivery elements 120 (as illustrated in Fig. 10d and described in previous sections) and emission through optical inter-balloon element 55 for dilating the occlusion (once the occlusion was first crossed) and for photodynamic therapy.

The various opto-mechanical designs, the various apparatus and methods described in relation to laser source 100 and control unit 110, the various designs for designing basic balloon body 2 and the bonding of external optical elements to basic balloon body 2, and other variations described in connection to the usage of externally attached optical fibers 3 are equally applicable to the usage of optical inter-balloon element 55 and externally attached optical elements 200.

Reference is now made to FIG.16, Fig 17a and Fig 17b that illustrate a fourth embodiment of the present invention. Externally attached thermo-mechanical elements 300 are attached or embedded in basic balloon body 2. With respect to Fig 17, light energy guide system 5 ends in optical inter-balloon element 55 capable emit radial light-energy. Externally attached thermo-mechanical elements 300 are capable of transforming light-energy emitted by inter-balloon section 54 into thermal energy and capable of delivering light induced thermal energy to blood vessel wall 150 and stenotic plaque 151. An additional optional intra-balloon focusing element 202 can be used to focus the radial light energy on thermo-mechanical elements 300 and/or on a confined volume adjacent to externally attached thermo-mechanical elements 300. Fig. 18b illustrates an alternative apparatus where optical guide inter-balloon section 54 includes several optical fibers each emitting radial light-energy in a specific section. Basic balloon body 2 can be coated in certain areas as to reflect the light-energy and provide additional focusing on the externally attached thermo-mechanical elements 300.

Externally attached thermo-mechanical elements 300 can be designed from various thermo-conductive materials. For example, attached thermo-mechanical elements 300 can be made from thermally conducting metal that is also thermally responsive to the light-energy emitted by optical-guide inter-balloon section 54. Optionally, attached thermo-mechanical elements 300 are coated on the side attached to basic balloon body 2 with light receptive materials that are thermally responsive

when exposed to certain light wavelengths. Thermo-mechanical elements 300 have a firm, yet flexible structure in order to ensure that during the inflation of basic balloon body 2 they exert an adequate pressure on the heated/bond-weakened tissue adjacent to them, while at the same time they assist during the endoluminal maneuvering of dilatation balloon catheter 1. Optionally, thermo-mechanical elements 300 are part of basic balloon body 2.

Still preferably, the light-energy is delivered in cycles, and in between the heating cycles thermo-mechanical elements 300 are cooled, for example by the contact with the liquid used to inflate basic balloon body 2. The heating/cooling cycle should preferably ensure that the temperature of the adjacent tissue is maintained between 60 to 80 degrees in a small volume of tissue proximal to thermo-mechanical elements 300. Once a required inflation level is achieved the heating is stopped and thermo-mechanical elements 300 stop acting as "thermal blades" in order to ensure that no unwanted damage is induced on vessel wall 150.

Externally attached thermo-mechanical elements 300 act as "thermal blades" creating longitudinal microscopic cuts in the stenotic plaque 151 through a combination of confined temperature-energy delivered to adjacent tissue in order to weaken the tissue bonds, and by the mechanical pressure of exerted in the exact area of tissue that was bond-weakened by heating. This effect assists the balloon inflation process, facilitating a smooth inflation regardless of the type of stenotic plaque.

The temperature of attached thermo-mechanical elements 300 can be controlled by various methods, for example by using the inflation liquid as a cooling material, that lowers the temperature during the periods when optical-guide inter-balloon section 54 is not emitting light-energy. This is particularly important in order to ensure that no irreversible damage is induced on cells at a distance of 150-200 microns from thermo-mechanical elements 300.

The controlled heating process described above can also be used for activating light-sensitive drugs as described in previous embodiments. According to one possible implementation the same wavelength is used for heating thermo-mechanical elements 300 in order to create the microscopic opto-mechanical cuts and also for the drug activation. According to an alternate implementation one type/set of wavelengths is used for heating thermo-mechanical elements 300 and another type/set of wavelengths is used for the drug activation. In the later case basic balloon body 2 can be coated in certain areas as to reflect the light-energy at the wavelength(s) used for heating

thermo-mechanical elements 300 and at the same time being transparent for the wavelength(s) used for drug activation.

An additional variation to the embodiments above is now described. A light energy guide system 5 includes an intermediary optical guide member 51 that is a liquid light-guide capable of transmitting light-energy to set of balloon externally attached optical fibers 31 through distal optical connector 52. Light energy guide system 5 includes an intermediary optical guide member 51 that is a liquid light-guide capable of transmitting light-energy to externally attached light focusing elements 200 or to externally attached thermo-mechanical elements 300, according to the implementation.

The usage of a liquid light-guide, can be implemented in several ways. According to one preferred embodiment the liquid used for inflating basic balloon body 2 is also used as a light-guide. The tube-like catheter body starts conducting light after the inflation of the balloon. In this case, the same connector can be used to inflate the balloon and to connect light-source 100 to light energy guide system. Alternately, the liquid used for inflating the balloon is introduced/taken-out through a standard lumen that is unrelated to the liquid wave-guide 5.

The various opto-mechanical designs, the various apparatus and methods described in relation to laser source 100 and control unit 110, the various designs for designing basic balloon body 2 and the bonding of external optical elements to basic balloon body 2, and other variations described in connection to the usage of externally attached optical fibers 3 are equally applicable to the usage of optical guide inter-balloon section 54 and externally attached thermo-mechanical elements 300.

Reference is now made to FIG.18 that illustrate a fifth embodiment of the present invention. Externally attached cryo-mechanical elements 400 are attached or embedded in basic balloon body 2. With respect to Fig 22, a cooling transfer lumen 402 is used for transferring a refrigerant agent, such as liquid nitrous oxide, from a cooling source 412 to for cooling externally attached cryo-mechanical elements 400, to a controlled temperature below zero degrees C. Cooling transfer lumen 402 ends in diffuse cooling tubes 404 that release the refrigerant agent in cooling tube 406 proximal to cryo-mechanical elements 400. As the refrigerant agent vaporizes inside cooling tube 406 the temperature drops and cools cryo-mechanical elements 400 and adjacent tissue. The transfer rate of the refrigerant agent is controlled in order to

ensure a required temperature of cryo-mechanical elements 400, and adjacent tissue preferably to a temperature around -5 C - -10 C.

Cryo-mechanical elements 400 can be made from various types of materials, for example, from a thermo-conductive metal. Alternately, cryo-mechanical elements 400 can be made of materials that transform into a rigid structure only when cooled to a certain temperature, and are malleable at higher temperatures. Still alternately cryo-mechanical elements 400 can consist from separate inflation chambers on the external perimeter of basic balloon body 2 that are coated with special materials such as nitinol wires or other similar materials reinforcing the outer structure. When cooled the material in the chambers creates a microscopic V-shaped structure that based on the reinforcing material coating the outer part of the chamber can "cut" the plaque or any other adjacent tissue. Optionally, the external chamber can be placed on a reinforcing basis. Optionally, still the above described cutting effect is achieved through regular inflation means without cooling the material.

The gas in cooling tube 406 escapes through an output gas lumen ending in a gas output port 412. Externally attached cryo-mechanical elements 400, and cooling tube 406, once cooled by the delivery of the refrigerant agent, are capable of cooling blood vessel wall 150 and stenotic plaque 151 in the area adjacent to externally attached cryo-mechanical elements 400. During the inflation of basic balloon body 2, the externally attached cryo-mechanical elements 400 pressure the tissue in the exact area that was first frozen/bond-weakened by the induced cryo-effect. Therefore, during the inflation process, externally attached cryo-mechanical elements 400 acts as microscopic "cryo blades" creating microscopic "cuts" or "cracks" in the atherosclerotic plaque 151 or thrombosis. The result is easier and more effective splitting or dissection of the atherosclerotic plaque 151 and easier inflation of basic balloon body 2 that can be performed gradually and at lower pressures than when using regular dilatation balloon catheters and causes less trauma to the vessel wall.

The "cryo blades" and in general delivery of radial confined cryo energy can be conducted regardless of whether a stent is already placed in the area to be treated without danger of mechanical obstruction or other interference.

Optionally, the freezing process is repeated several times where between the freezing periods the temperature of tissue increases. Such temperature cycles during the inflation can assist the "cryo-blade effect", enhances the "cracks" in the confined tissue volumes affected by the temperature cycles, minimizes clinical risks in cases of

severe atheromatosis, and can overcome easier heavily calcified atherosclerotic plaque. In severe cases, if required, basic balloon body can be re-inflated and delivery of radial confined cryo energy can be repeated to a required lumen segment. Still optionally, rotation of basic balloon body 2 in order to create multiple cuts can also be performed if clinically required.

Optionally, radial confined cryo energy can also be delivered after the successful inflation of basic balloon body 2 in order to create longitudinal microscopic cryo effects that can prevent generation of prolific hyperplasia and therefore acute restenosis following the PTA procedure.

The various mechanical designs, the various designs for designing basic balloon body 2 and the bonding of external elements to basic balloon body 2, and other variations described in connection to the usage of externally attached optical fibers 3 are equally applicable to the usage of externally attached cryo-mechanical elements 400.

Reference is now made to FIG.19a that illustrate a sixth embodiment of the present invention. Externally attached thermo-mechanical elements 500 are attached or embedded in basic balloon body 2. With respect to Fig 19a, RF/magnetic energy generating system 510 ends in an antenna that can emit RF-energy. Externally attached thermo-mechanical elements 500 are capable of transforming the RF-energy emitted by antenna 540 into thermal energy and capable of delivering RF induced thermal energy to blood vessel wall 150 and stenotic plaque 151. Fig. 19b illustrates an alternative apparatus where antenna 540 is inserted in balloon catheter 1.

Fig. 19c illustrates an alternative design of the sixth embodiment where externally attached thermo-mechanical elements 500 are directly connected to an RF energy source and capable of delivering RF induced thermal energy to blood vessel wall 150 and stenotic plaque 151.

The waveform of the energy source used in connection to the embodiments illustrated in Figs. 19a – 19c is selected in the form of pulses or train of pulses that do not induce thermal damage to the surrounding tissue beyond a very confined radius, preferably of less than 20-50 microns around externally attached thermo-mechanical elements 500.

Externally attached thermo-mechanical elements 500 can be designed from various materials with a desired permeability. For example, attached thermo-mechanical elements 300 are made from thermally conducting metal that is also

responsive to the RF-energy emitted by antenna 540. Optionally, attached thermo-mechanical elements 500 are part of the basic balloon body where the achieved thermo-mechanical effect is proportional to the perimeter size of basic balloon body 2. Thermo-mechanical elements 500 have a firm, yet flexible structure in order to ensure that during the inflation of basic balloon body 2 they exert an adequate pressure on the heated/bond-weekend tissue adjacent to them, while at the same time they assist during the endoluminal maneuvering of dilatation balloon catheter 1.. Still preferably, the RF-energy is delivered in short cycles, and in between the thermo-mechanical elements 500 are cooled, for example by the contact with the liquid used to inflate basic balloon body 2. According to a preferred option the heating/cooling cycle should preferably ensure that the temperature of the adjacent tissue is maintained between 60 to 80 degrees (or sometimes above 80 degrees) in a small volume proximal to thermo-mechanical elements 500. According to an alternative option the heating cycle is very short in duration, particularly shorter than the thermal diffusion time of the tissue (duration of pulses can be of microsecond magnitude) and the energy is high enough ensuring that most or all of the absorbed energy is converted into tissue vaporization and ejection of the products. This operation mode was referenced as Collateral-Damage-Free Ablation (CDFA).

Externally attached thermo-mechanical elements 500 induce thermo-mechanical effects that assist the balloon inflation process, and in combination with proper design of basic balloon body 2 and the design of the inflation system and the inflation method enable to dilate the stenotic segment at lower pressures without inducing thermal damage to vessel wall tissue. In this case the thermo-mechanical microscopic cuts in the stenotic plaque 151 are created by the confined temperature-energy and the mechanical pressure of externally attached thermo-mechanical elements 500 instead of through the externally attached light delivery means described in the first embodiment. Externally attached thermo-mechanical elements 500 are also capable of activating light sensitive drugs as described in previous embodiments.

Optionally, the antenna is the antenna of an MR imaging device, and the thermo-mechanical elements interact with the MRI magnetic field - static and transient fields induced during MR imaging. In such a case upon knowing the position of thermo-mechanical elements 500 by regular means (simple imaging or positioning based on magnetic sensing) the MR can send special transient fields in order to

receive an optimal thermal effect. Particularly, the intensity and direction of a gradient magnetic field can be chosen according to the calculated position of the thermo-mechanical elements 500 and the perimeter size of basic balloon body 2. The perimeter size of basic balloon body 2 is particularly important in the case where the thermal effect is based on the effect of a changing magnetic field through a cross-section of thermo-mechanical elements 500.

The various mechanical designs, the various designs for designing basic balloon body 2 and the bonding of external elements to basic balloon body 2, and other variations described in connection to the usage of externally attached optical fibers 3 are equally applicable to the usage of externally attached thermo-mechanical elements 500. All the designs and variations described in connection to the basic balloon body 2, the mechanical properties of basic balloon body 2 and externally attached thermo-mechanical elements 500, the inflation rate and lower inflation pressure described in connection to the first and second preferred embodiments are equally applicable to the sixth embodiment.

Numerous modifications and variations of the present invention are possible in light of the above teaching. Particularly, the dilatation balloon catheter and methods disclosed in the current invention can be used in PTA procedures in the vascular system, urinary system, biliary system or gastrointestinal system. The dilatation balloon catheters and methods disclosed in the current invention can be used in PTA procedures in humans or mammalian animals. Although the invention has been described and illustrated in detail, the above descriptions and illustrations have been offered for illustrative purposes only, and is not intended to limit the scope of the invention of this application.

## **CLAIMS**

1. A dilatation balloon catheter for endoluminal interventions as described in the above specification and illustrated in the attached figures.

2. A method for endoluminal interventions as described in the above specification and illustrated in the attached figures.

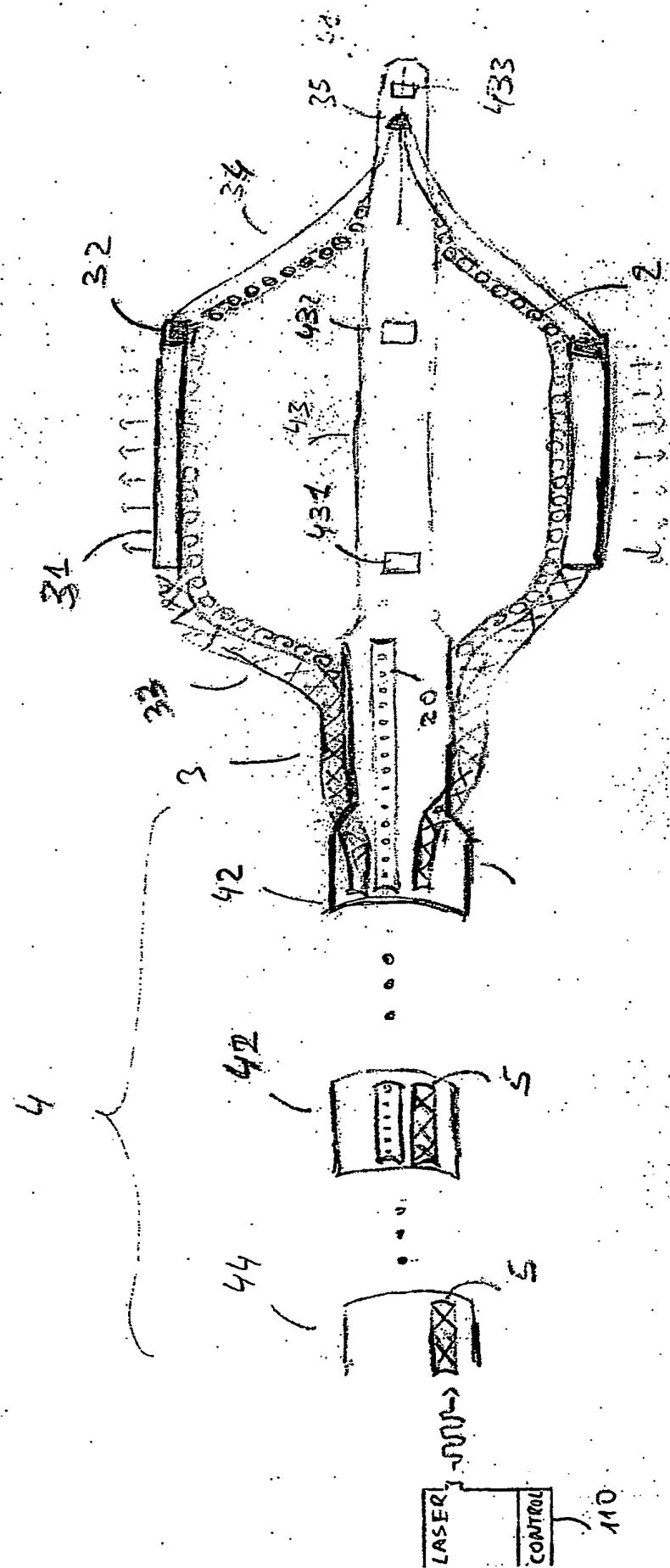


Fig. 1

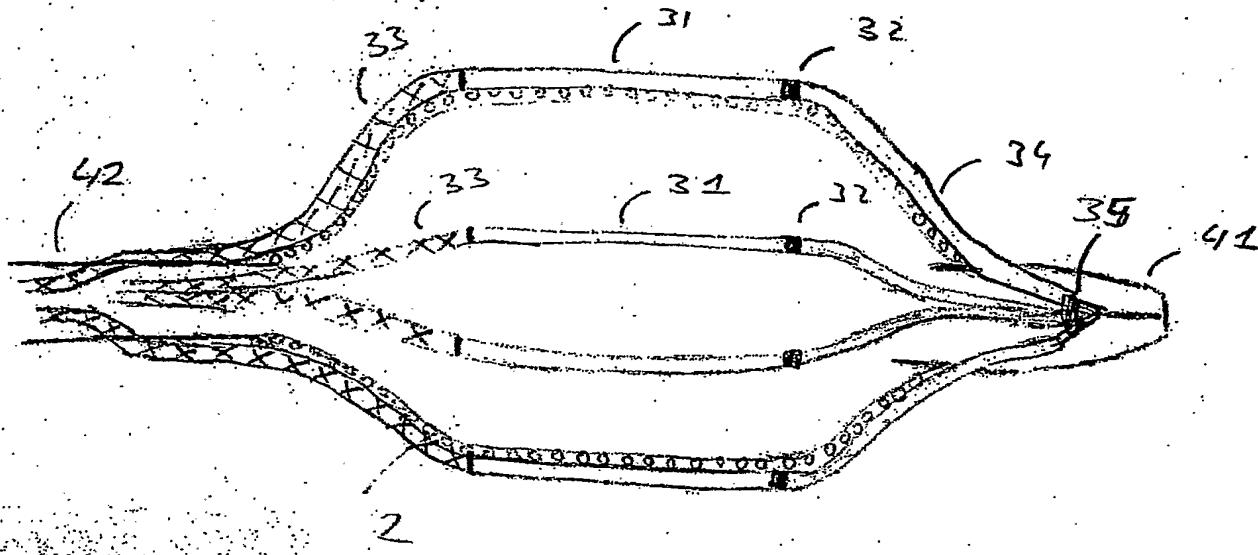


Fig. 2a.

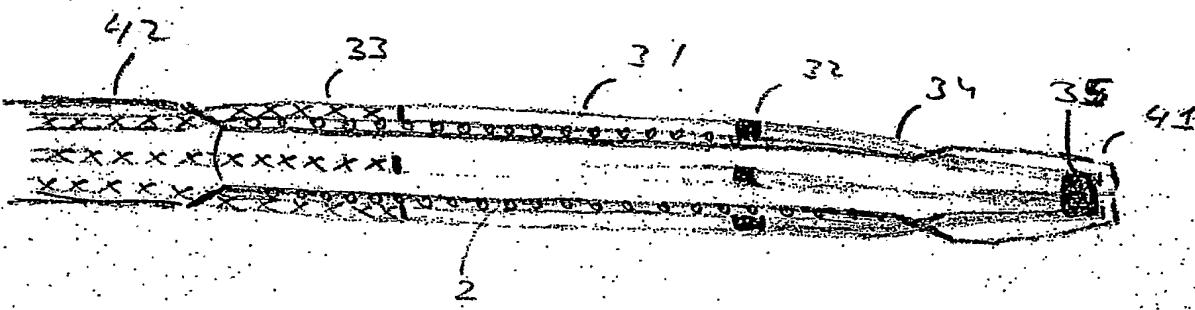


Fig. 2b.

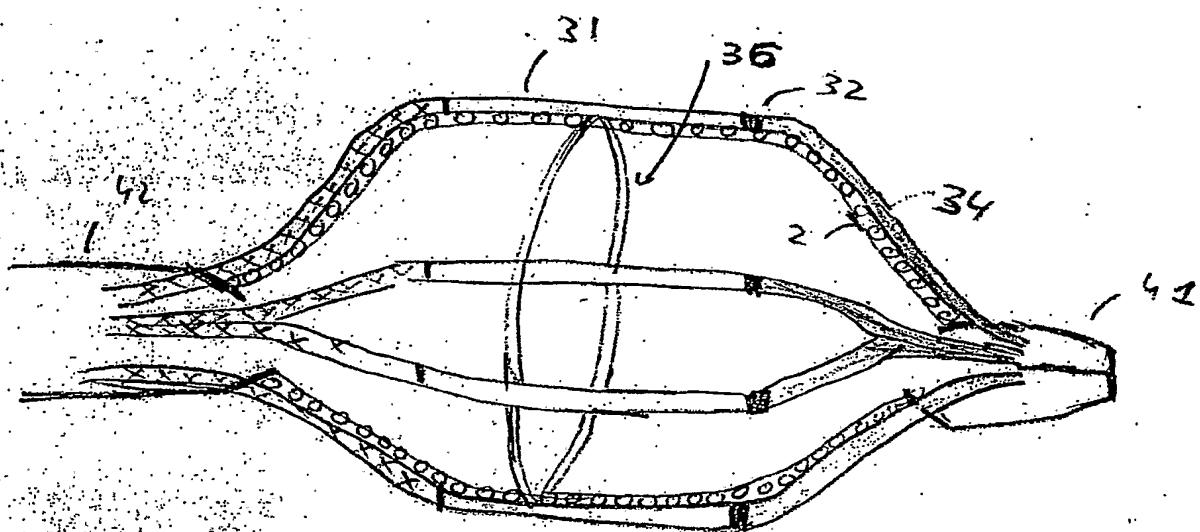


Fig. 2C

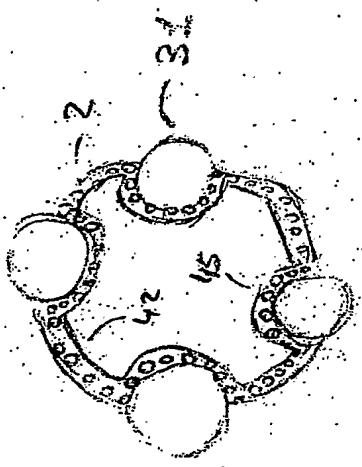


Fig. 31

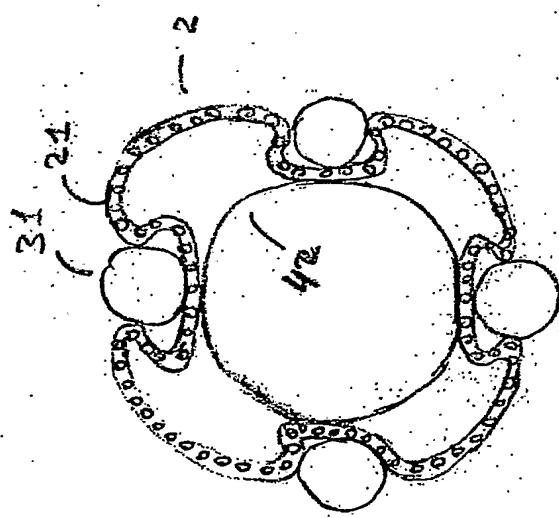
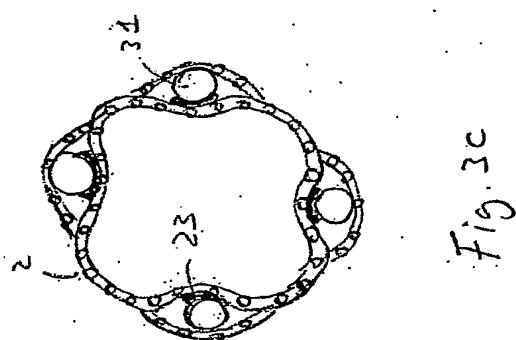
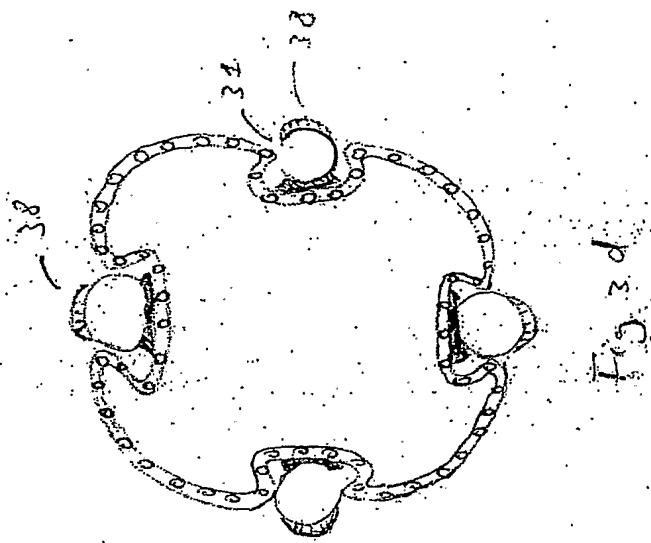


Fig. 32



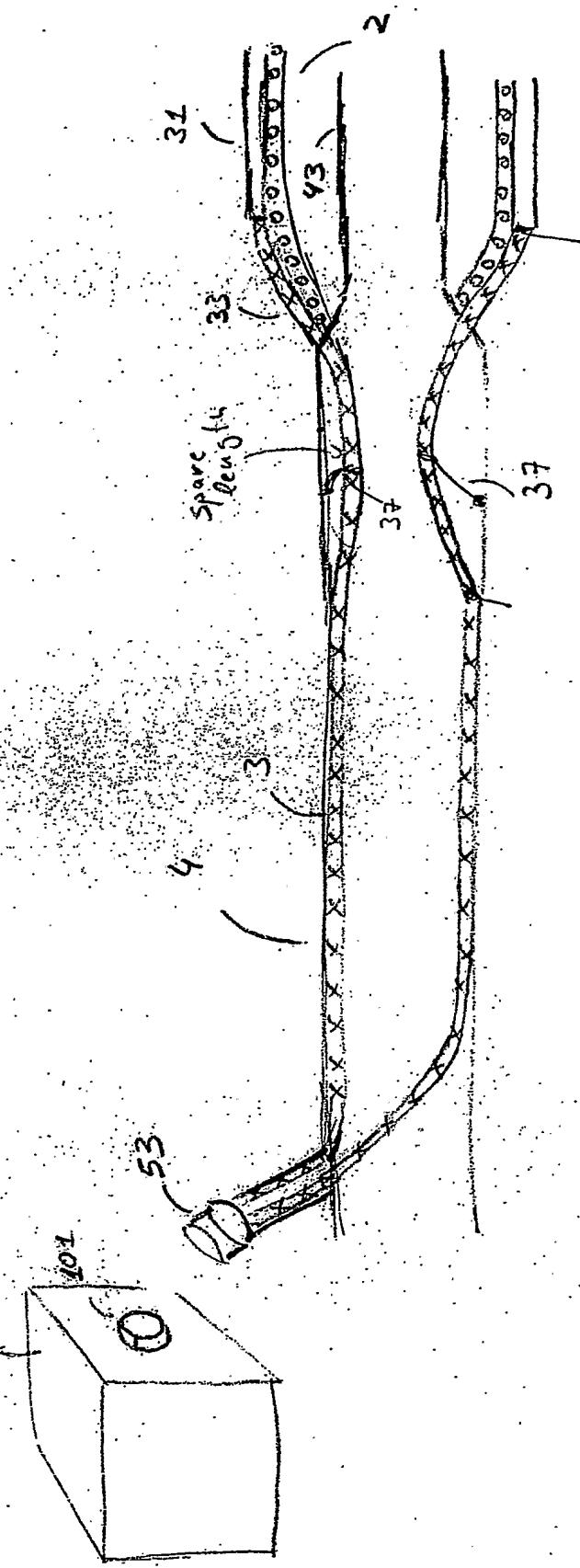


Fig. 4a.

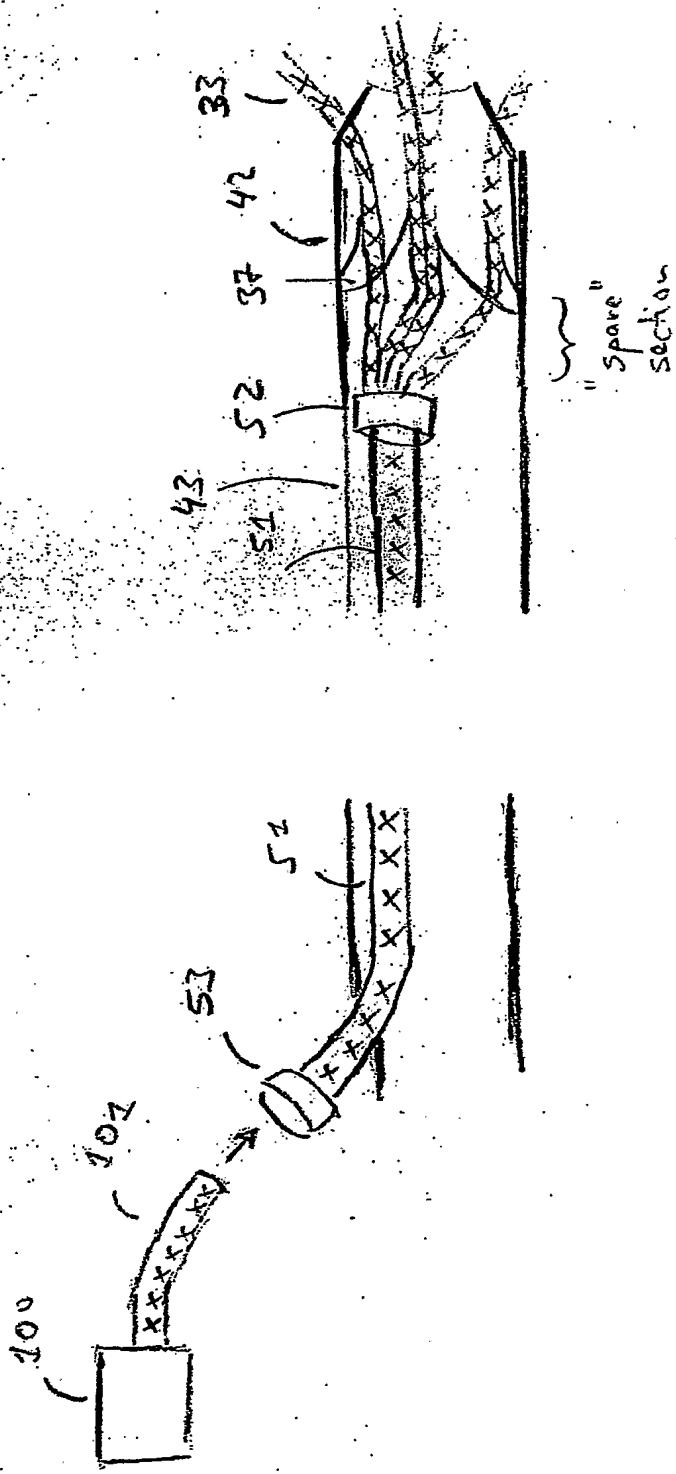


Fig. 46



Fig. 55

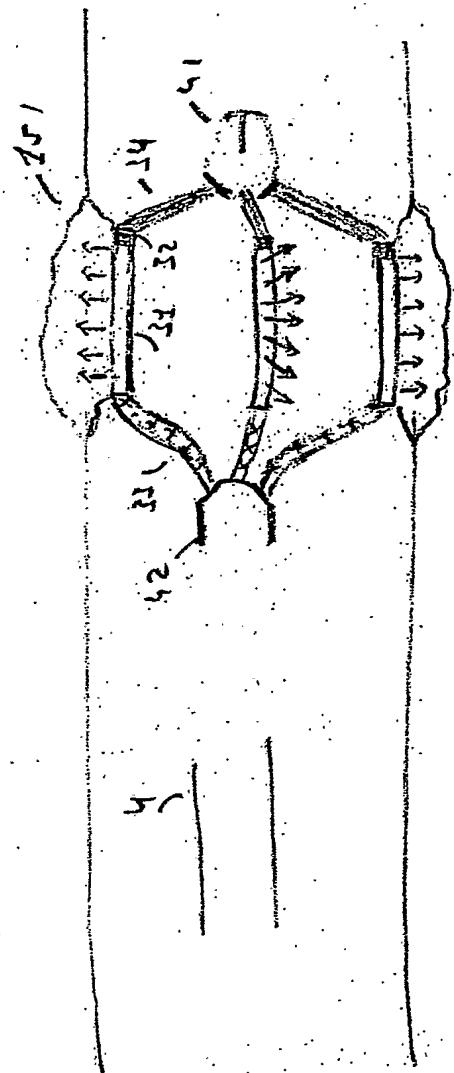


Fig. 56

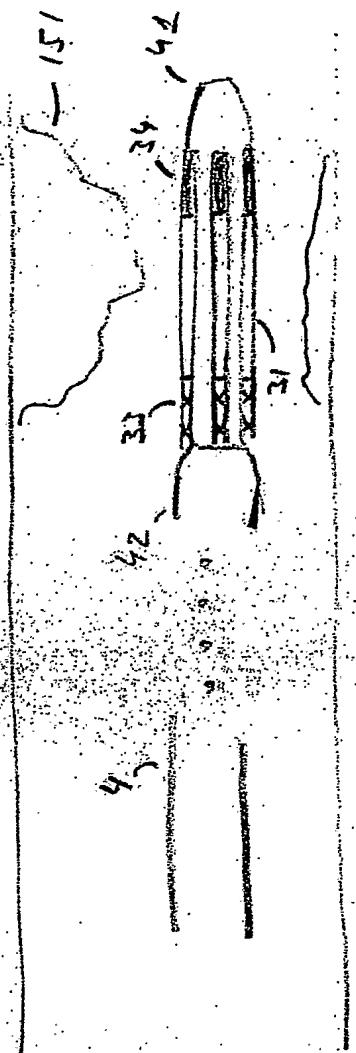


Fig. 5c

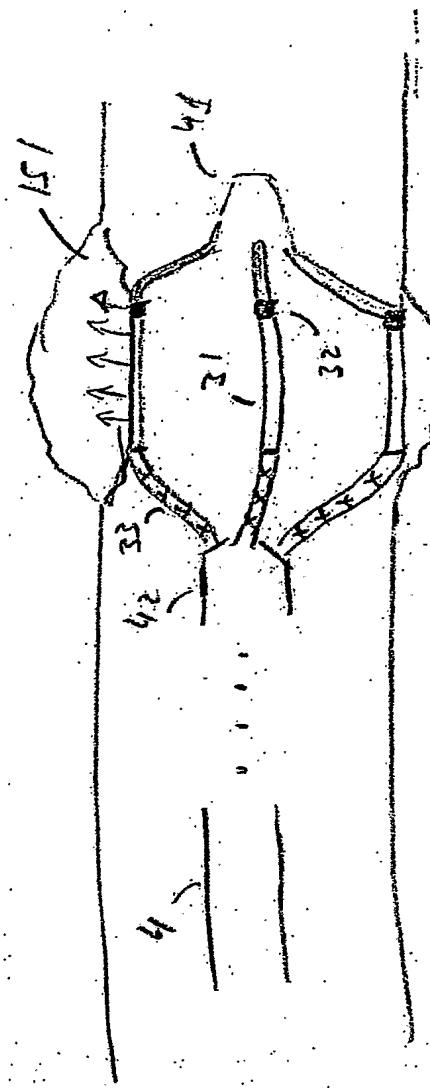


Fig. 5d

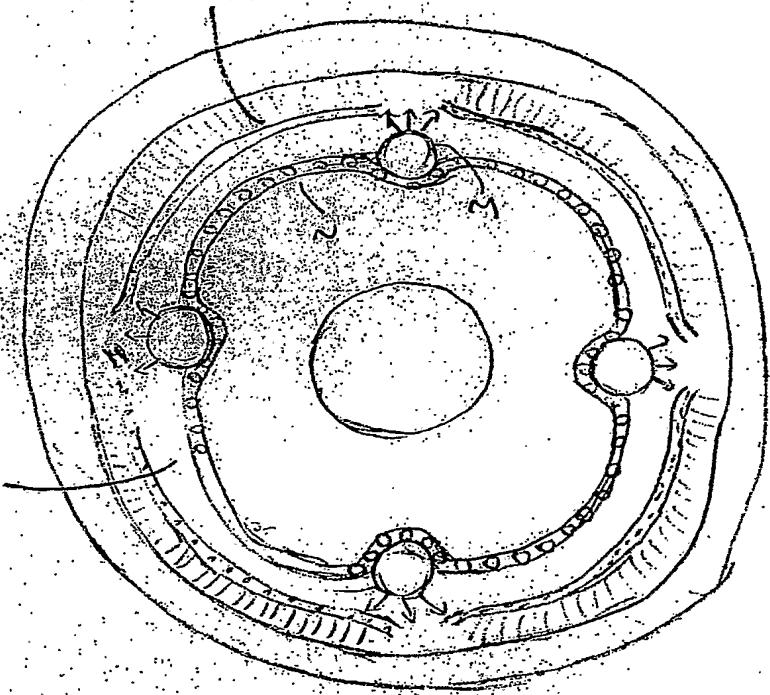


Fig 6a  
Fig 6b

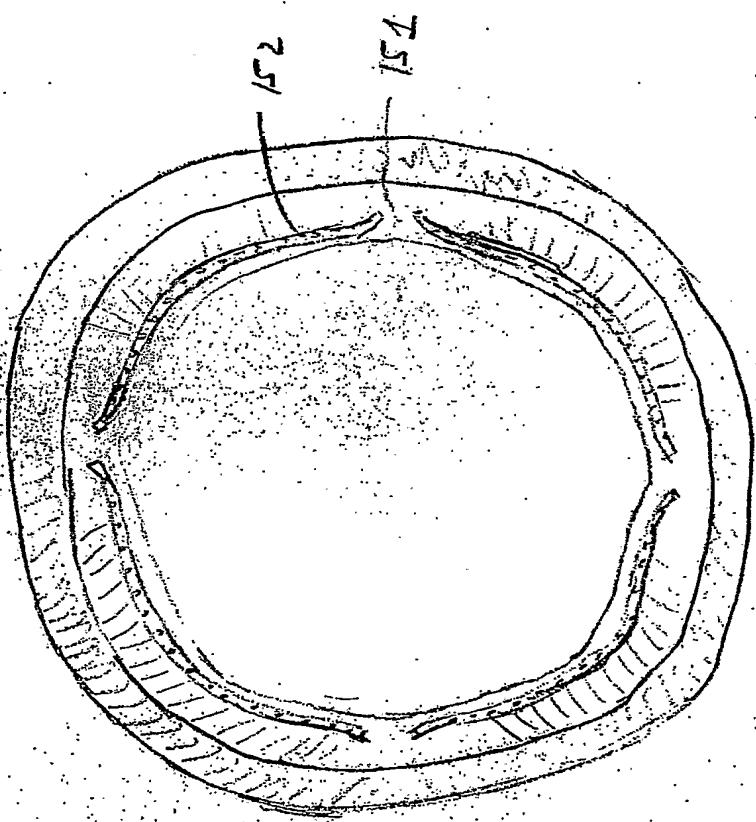


Fig 66

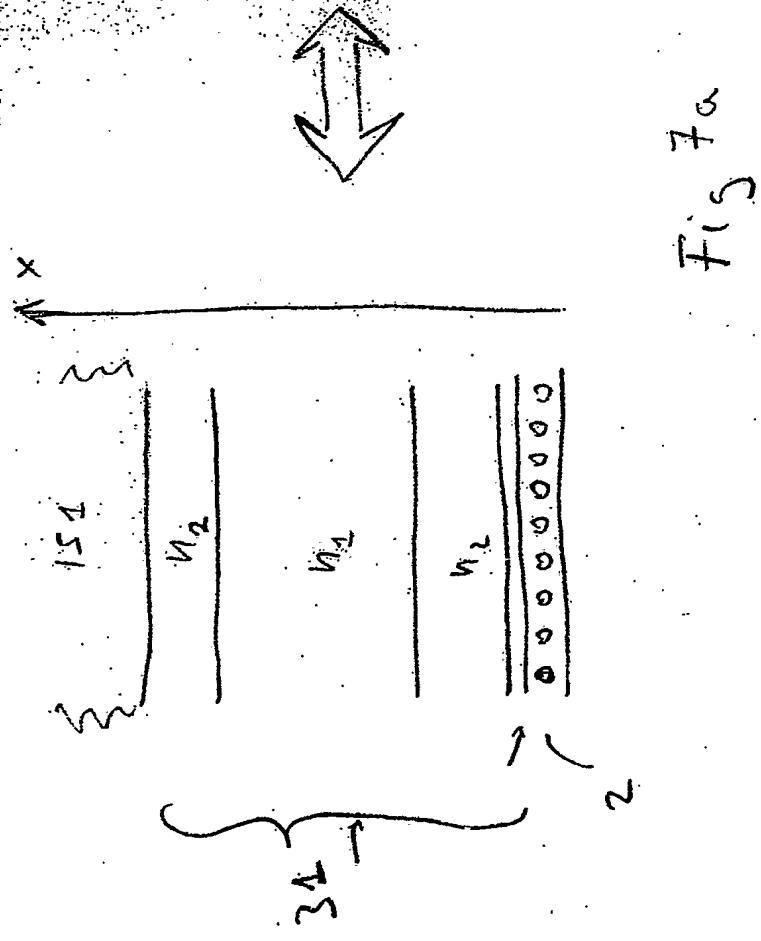
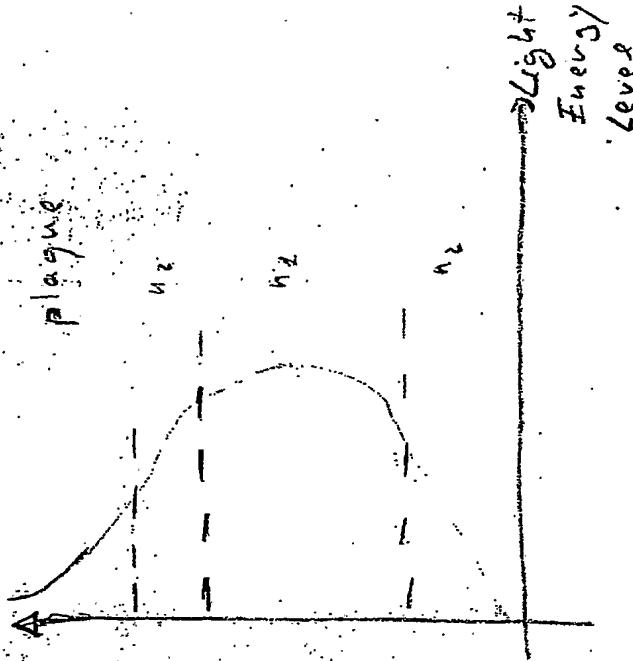


Fig 7a

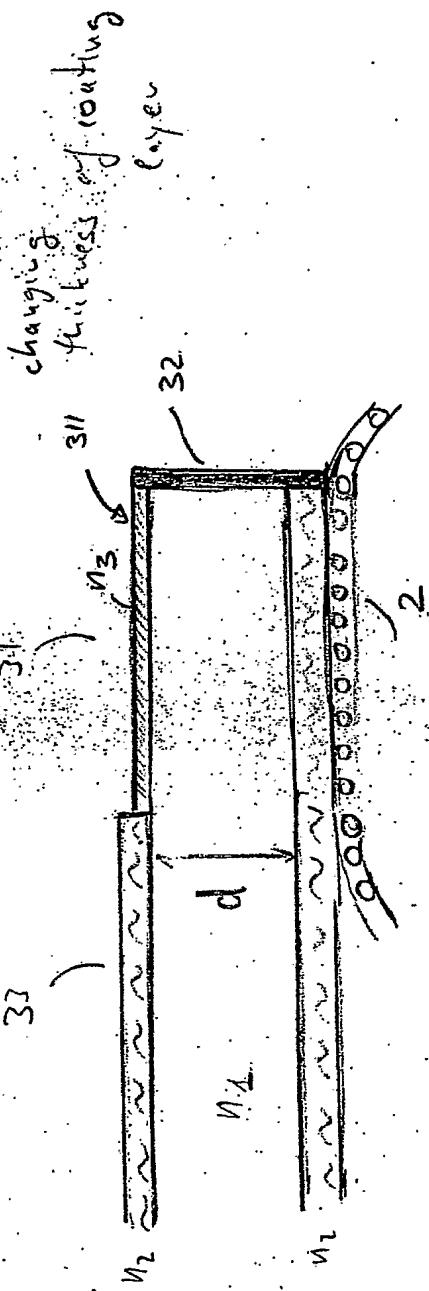


Fig. 76

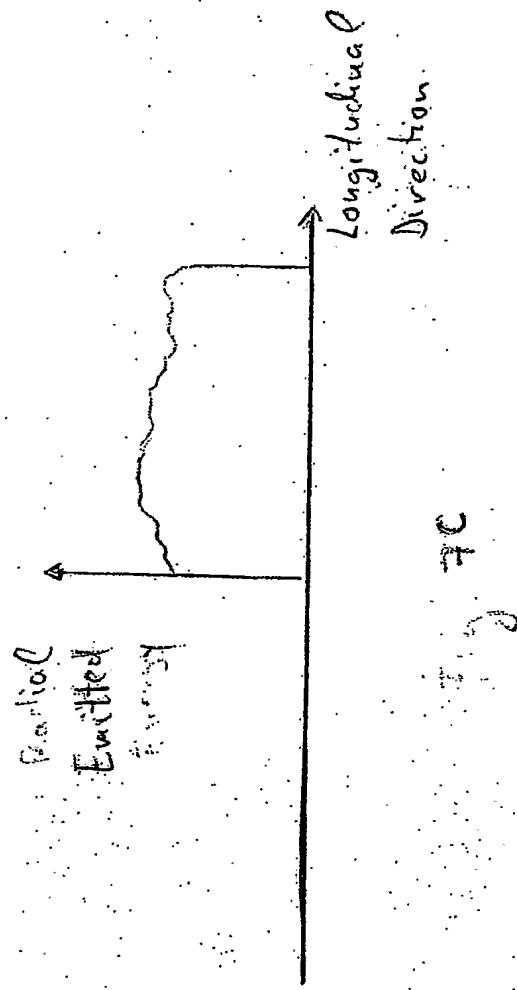




Fig. 8a

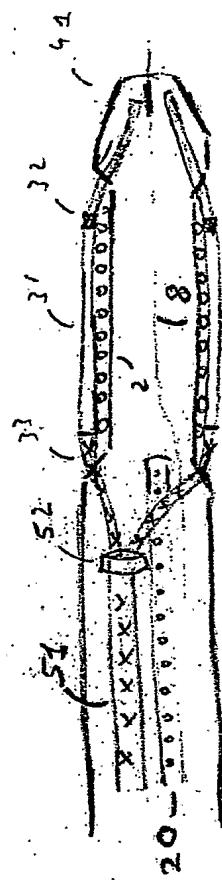
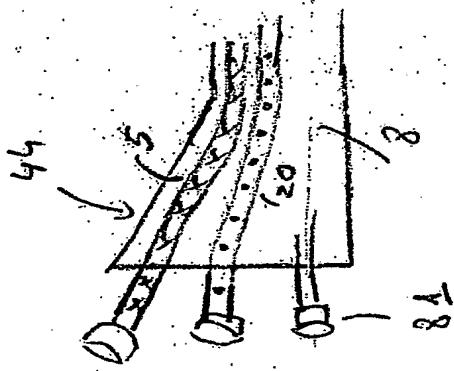
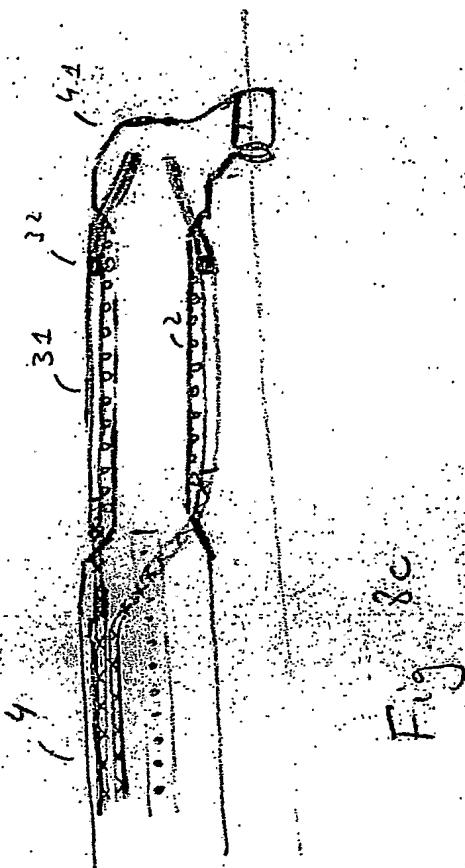


Fig. 8b





Copy provided by USPTO from the IFW Image Database on 02/28/2005

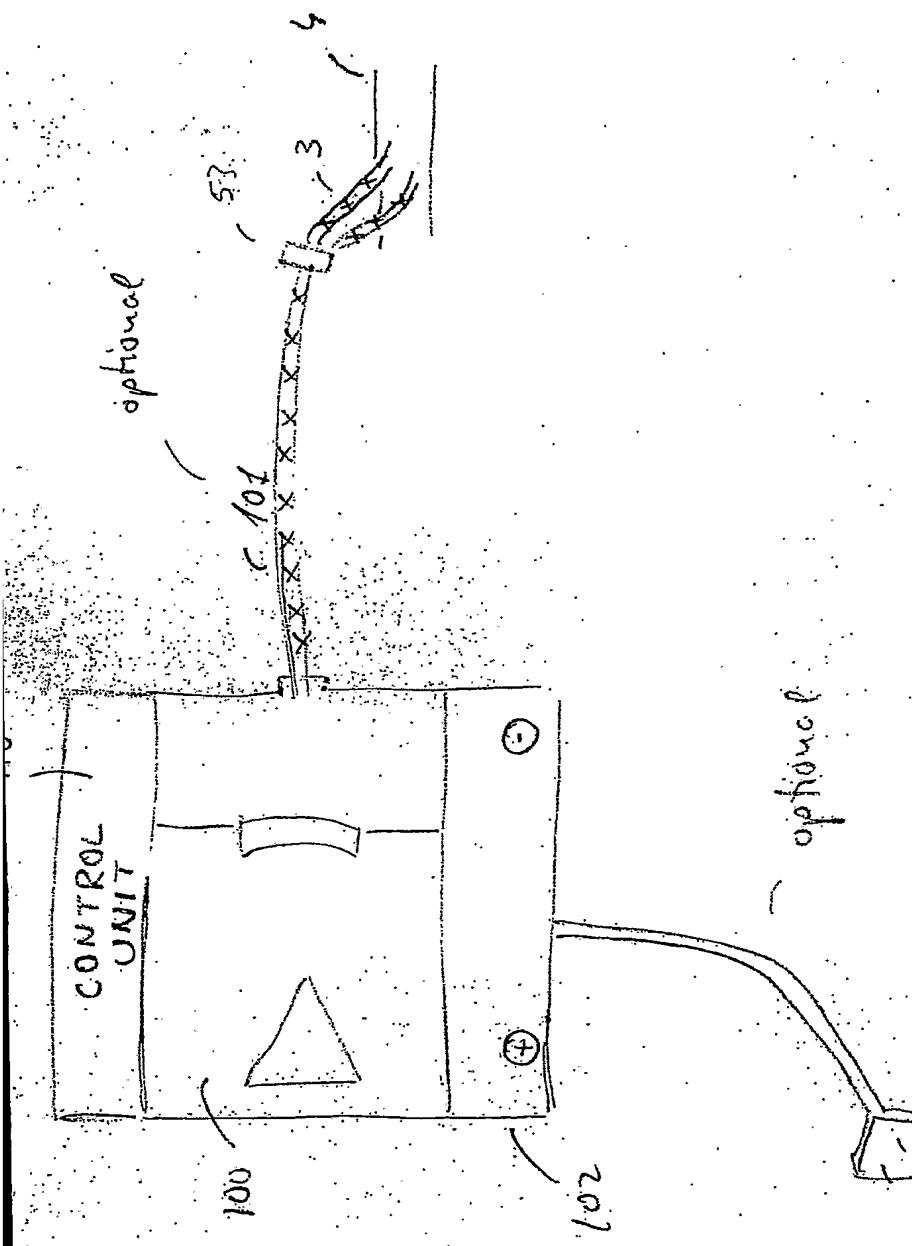


Fig. 9

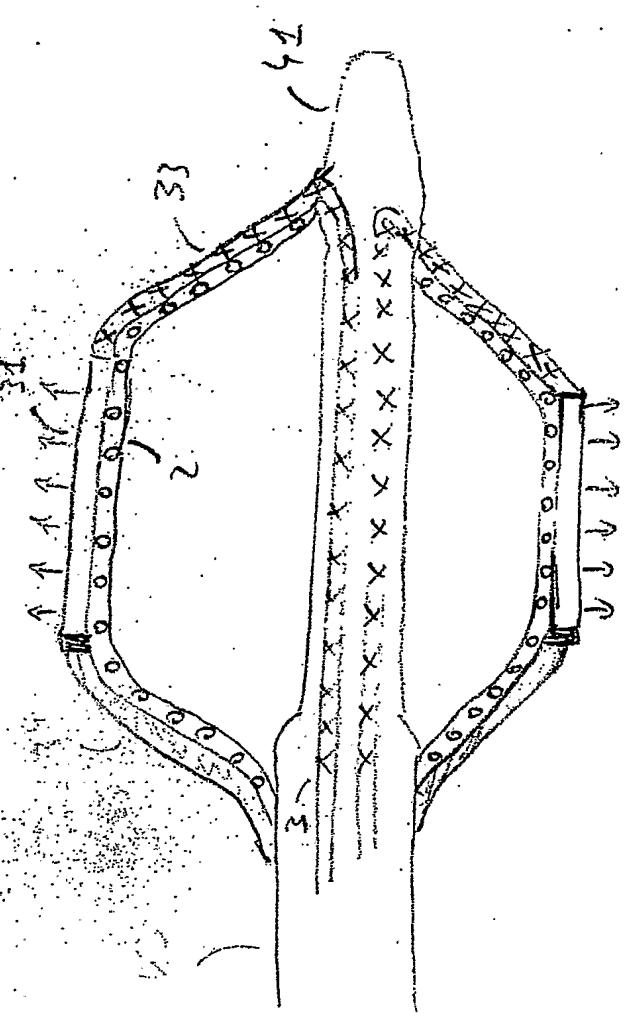


Fig 10 a

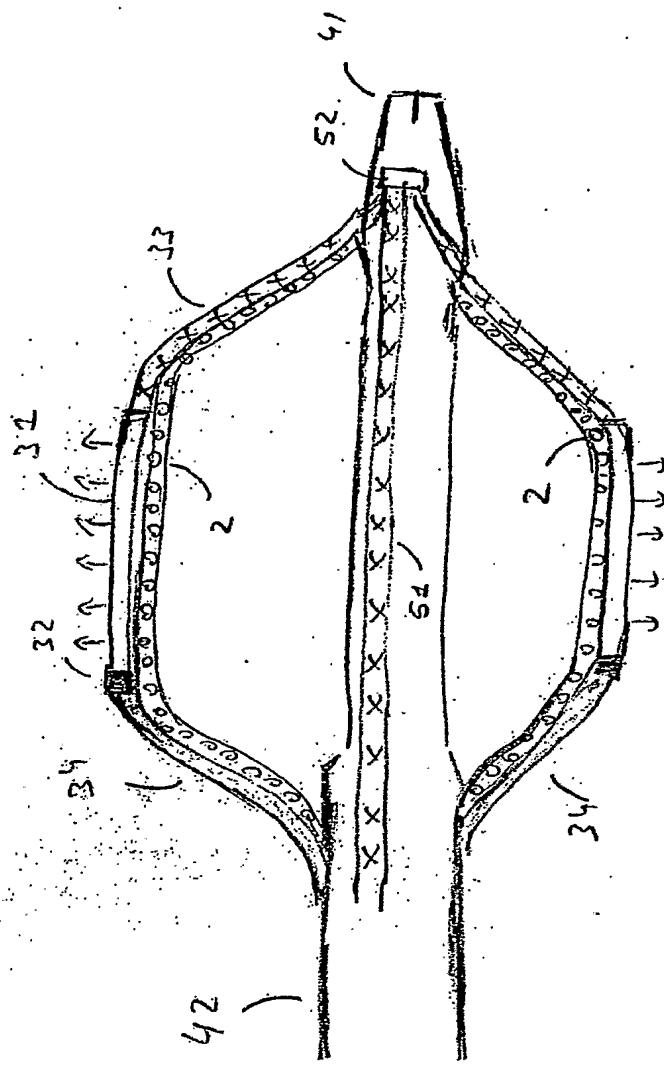
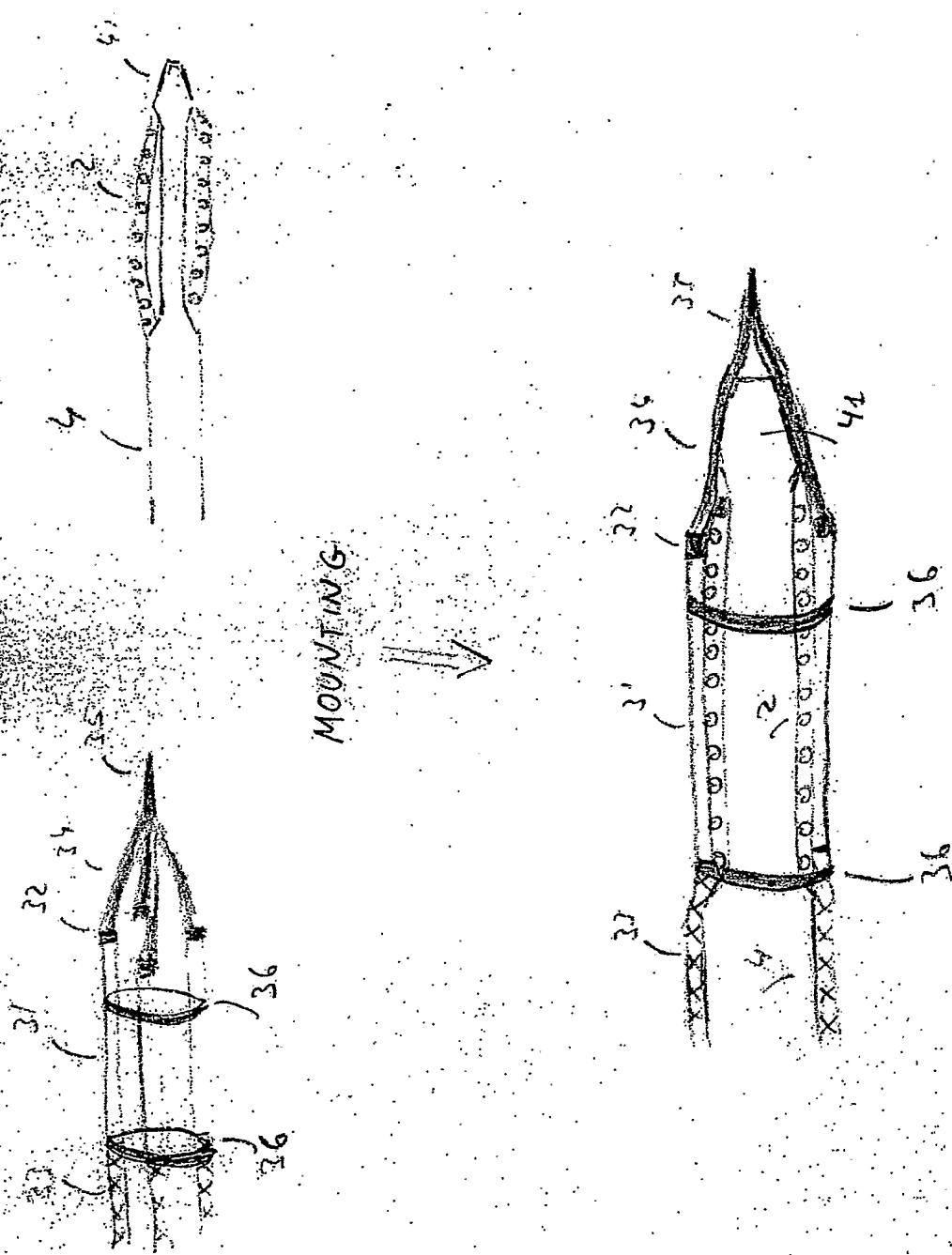


Fig 106

Fig. 10c



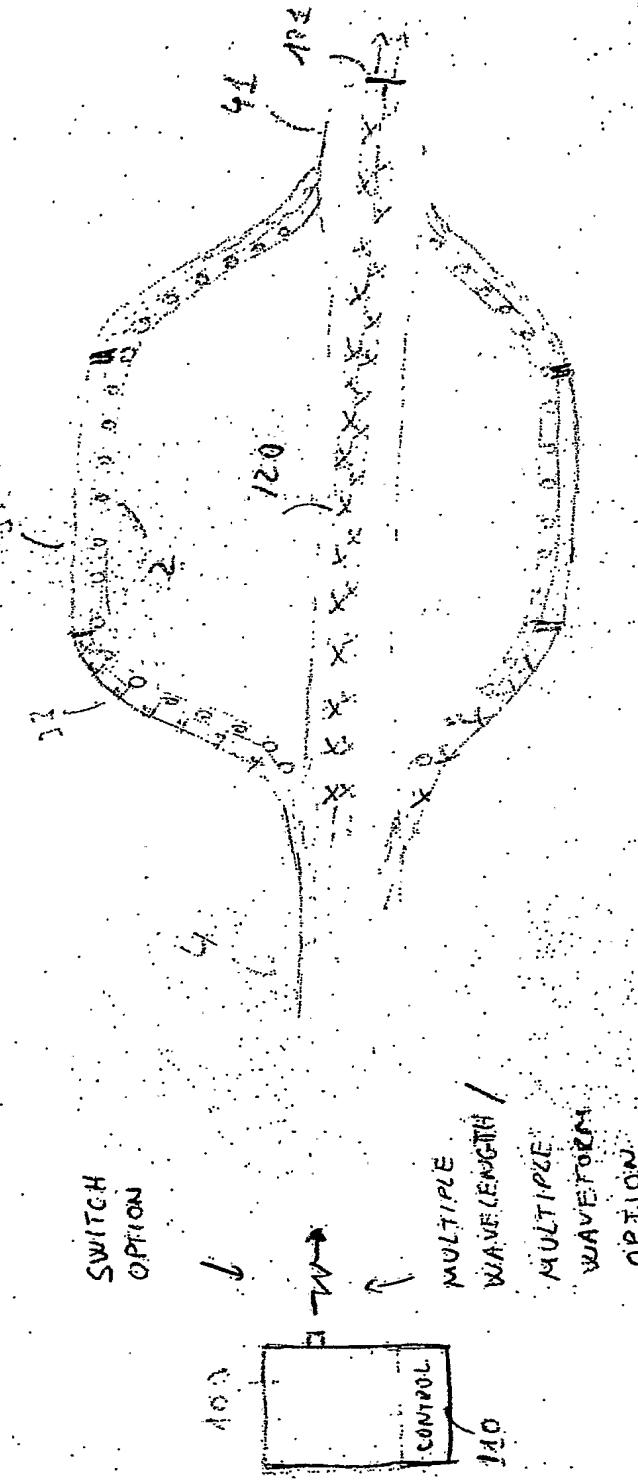


Fig 10d

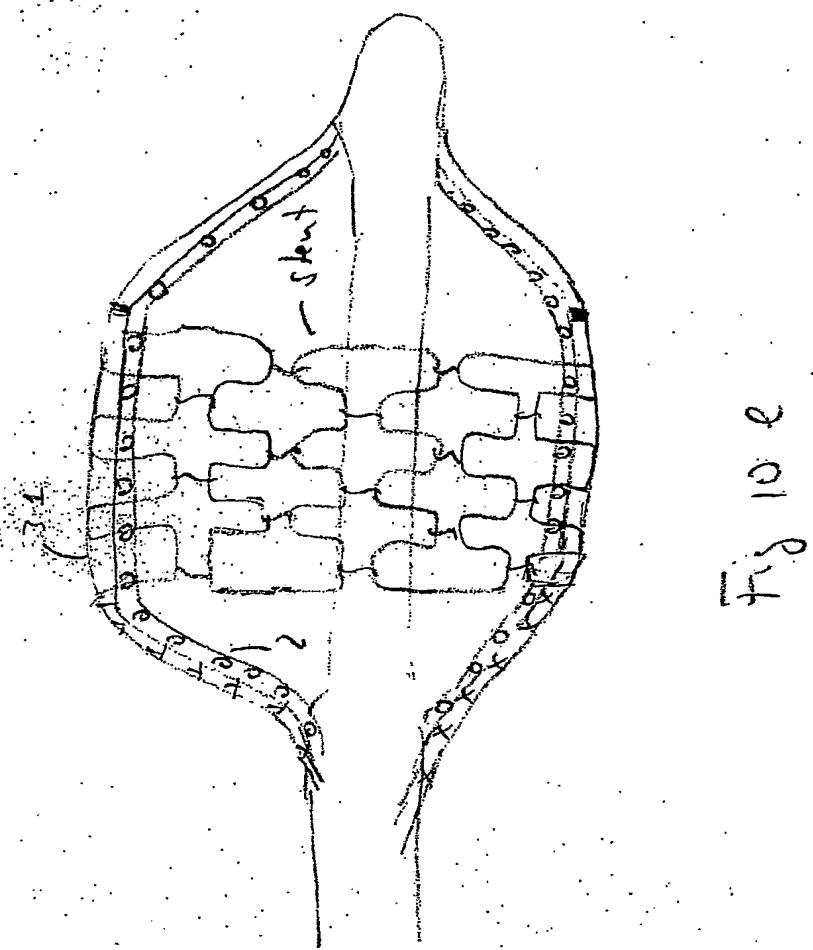
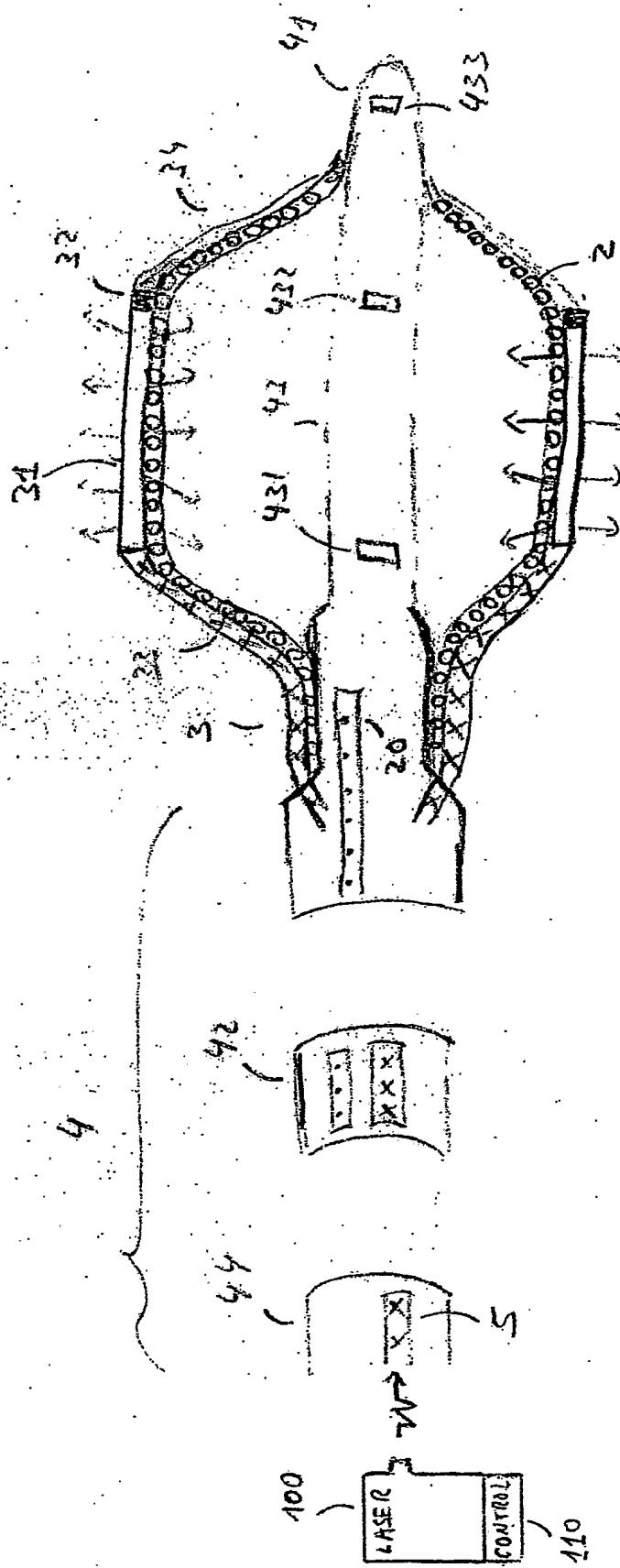


Fig. 41a



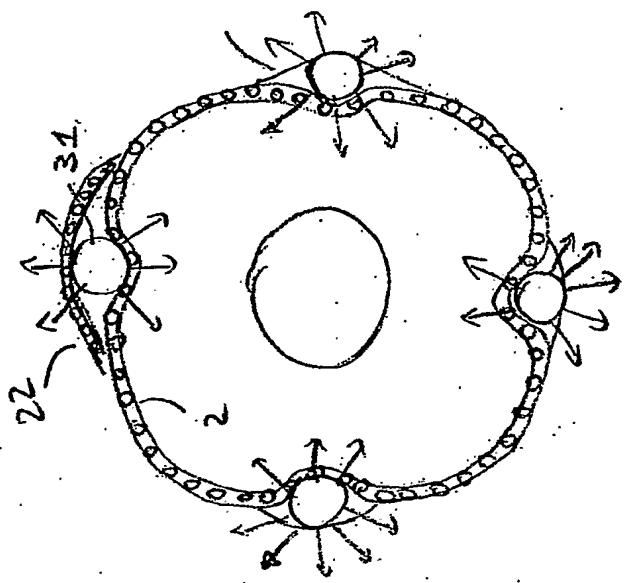


Fig. 12 b

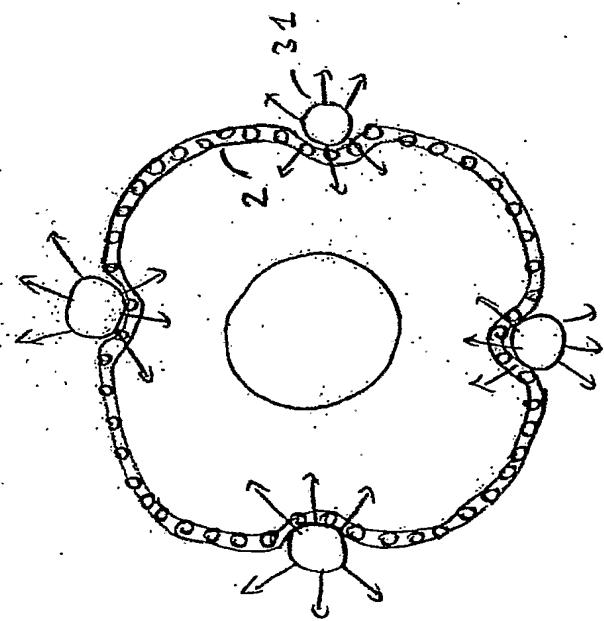


Fig. 12 a



Fig. 13a

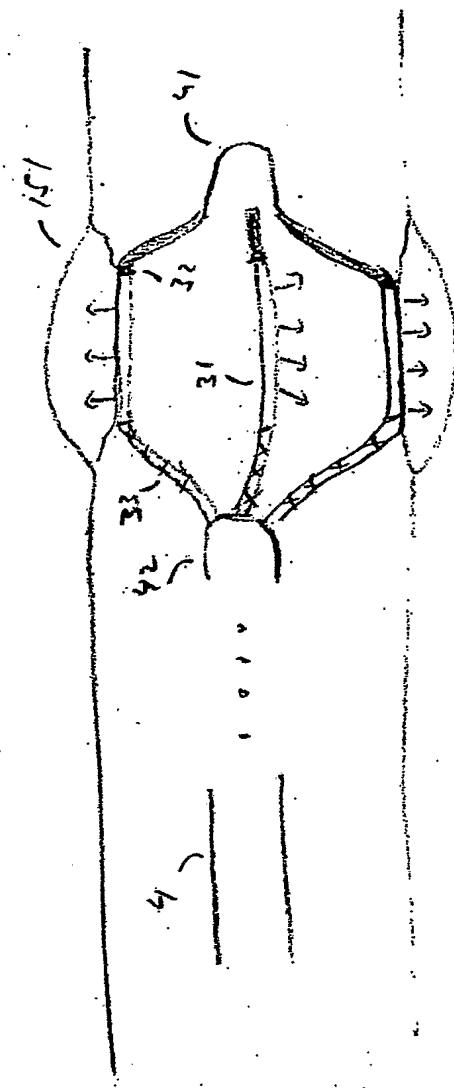
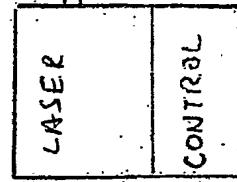
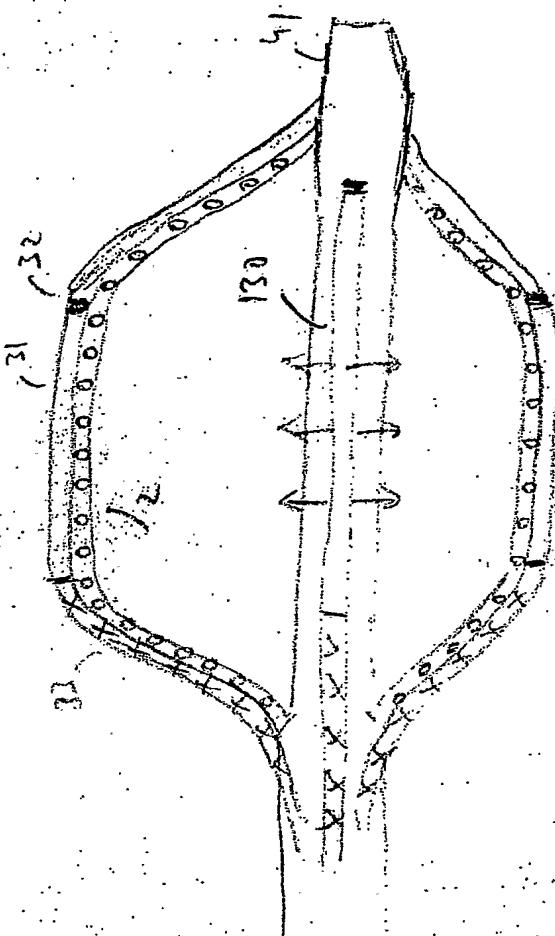


Fig. 13b

SOURCE / MULTIPLEXING

OPTION



MULTIPLY

WAVELENGTH /

MULTIPLY

WAVEFORM /

OPTION

Fig. 41b

Fig. 41c

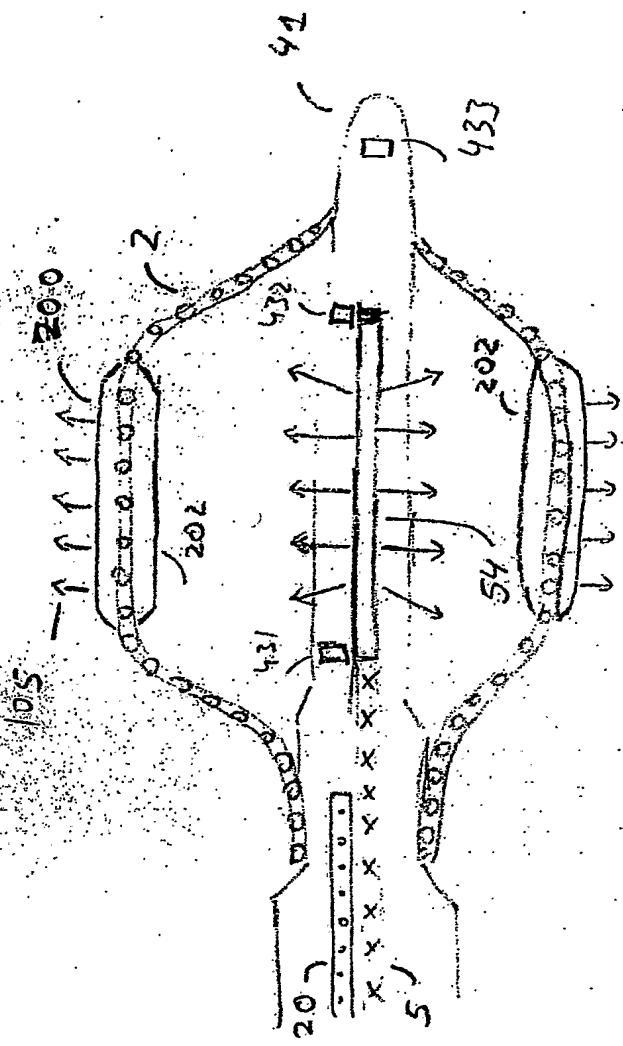


Fig 14

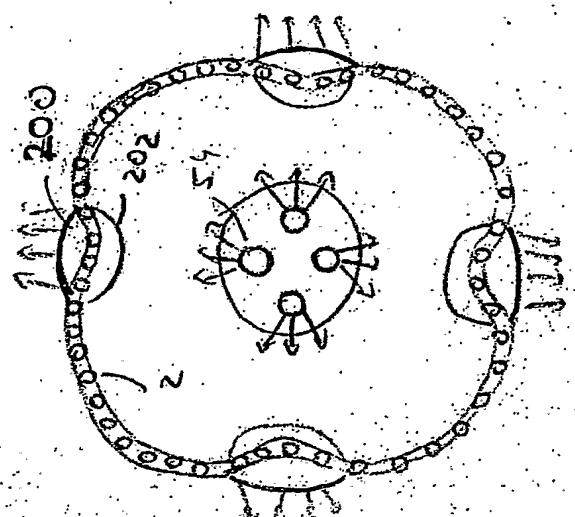


Fig. 155

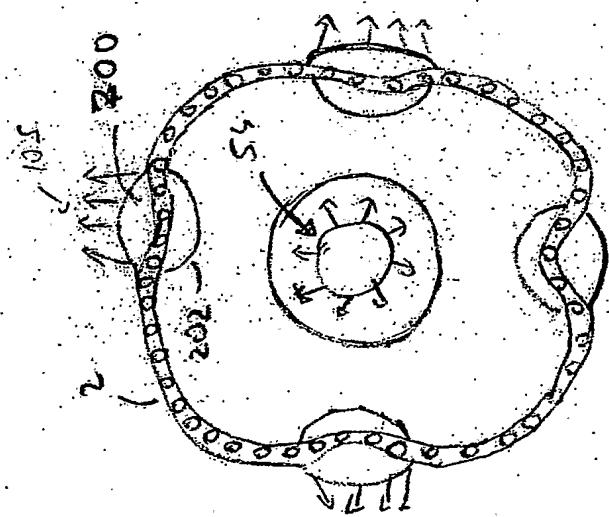


Fig. 15a

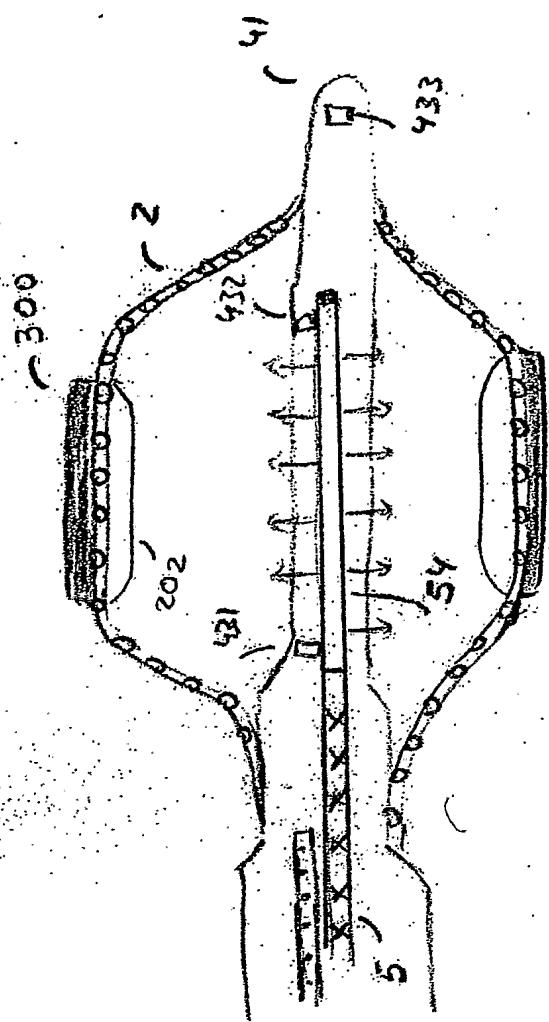


Fig. 16

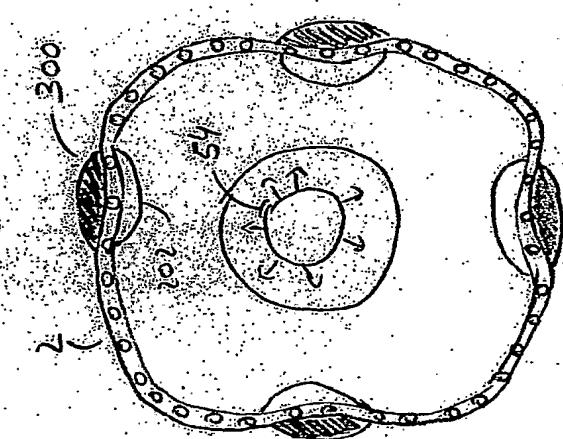


Fig 17a

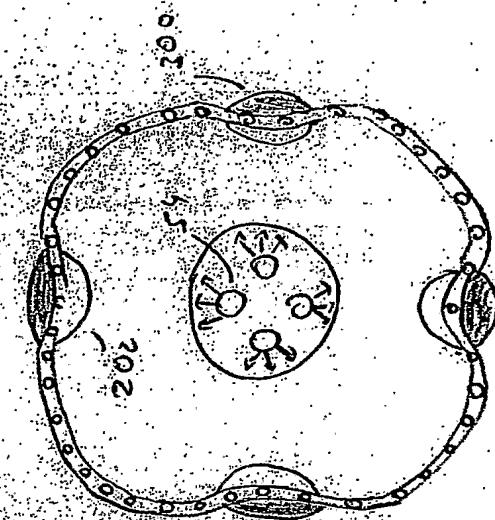


Fig 17b

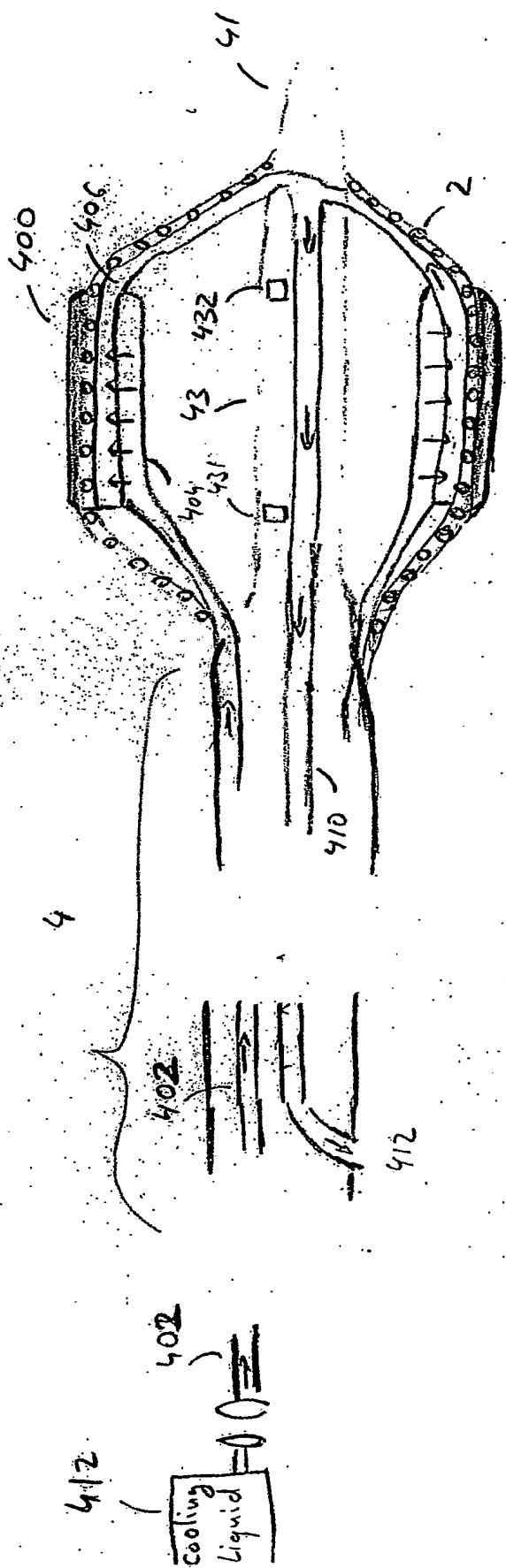


Fig. 18

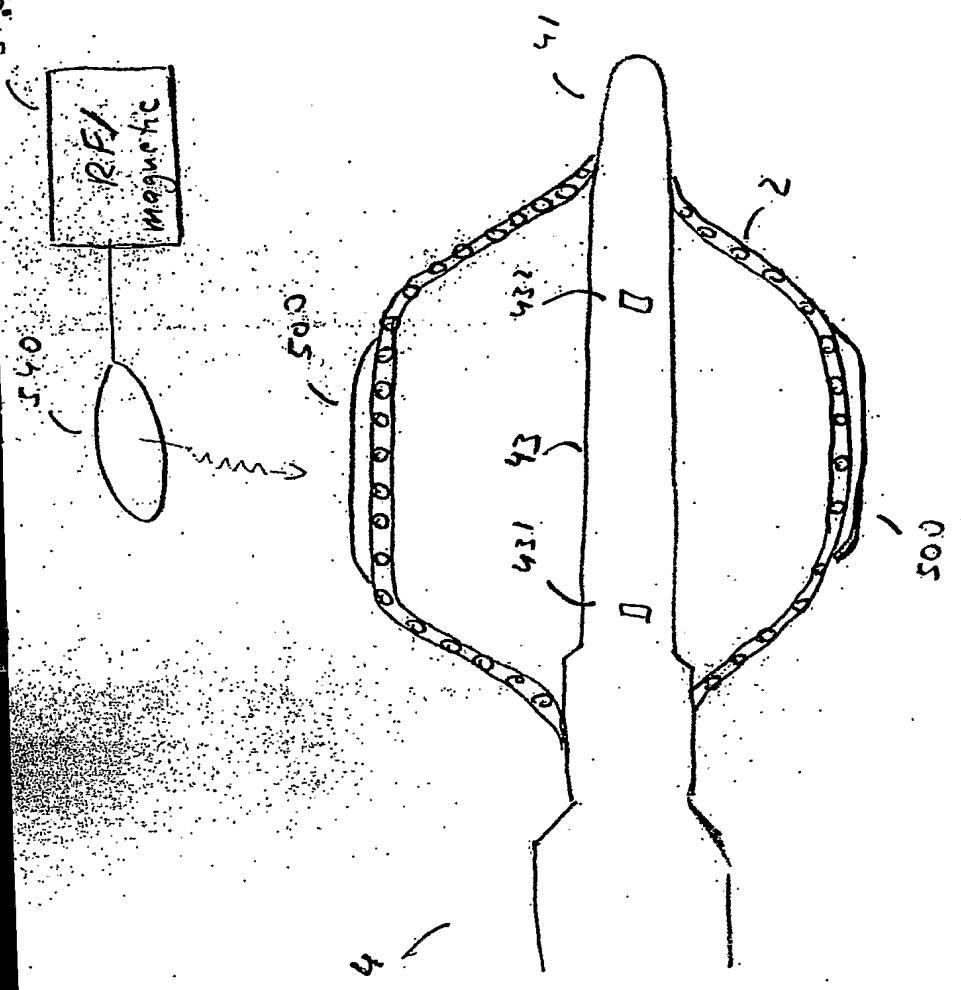


Fig 19 a

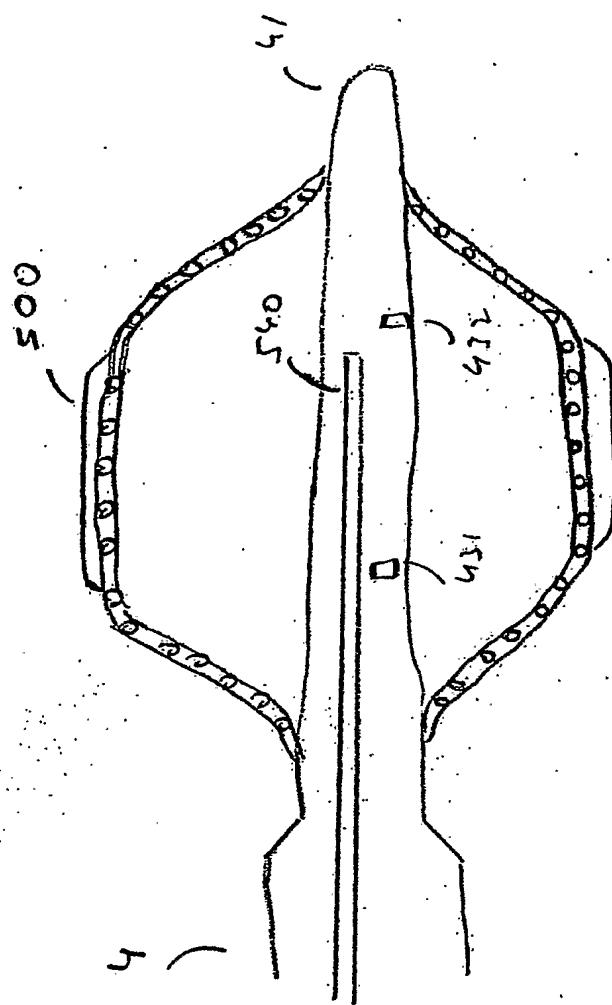
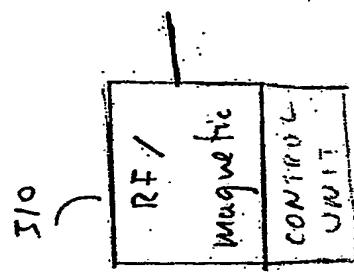


Fig. 196



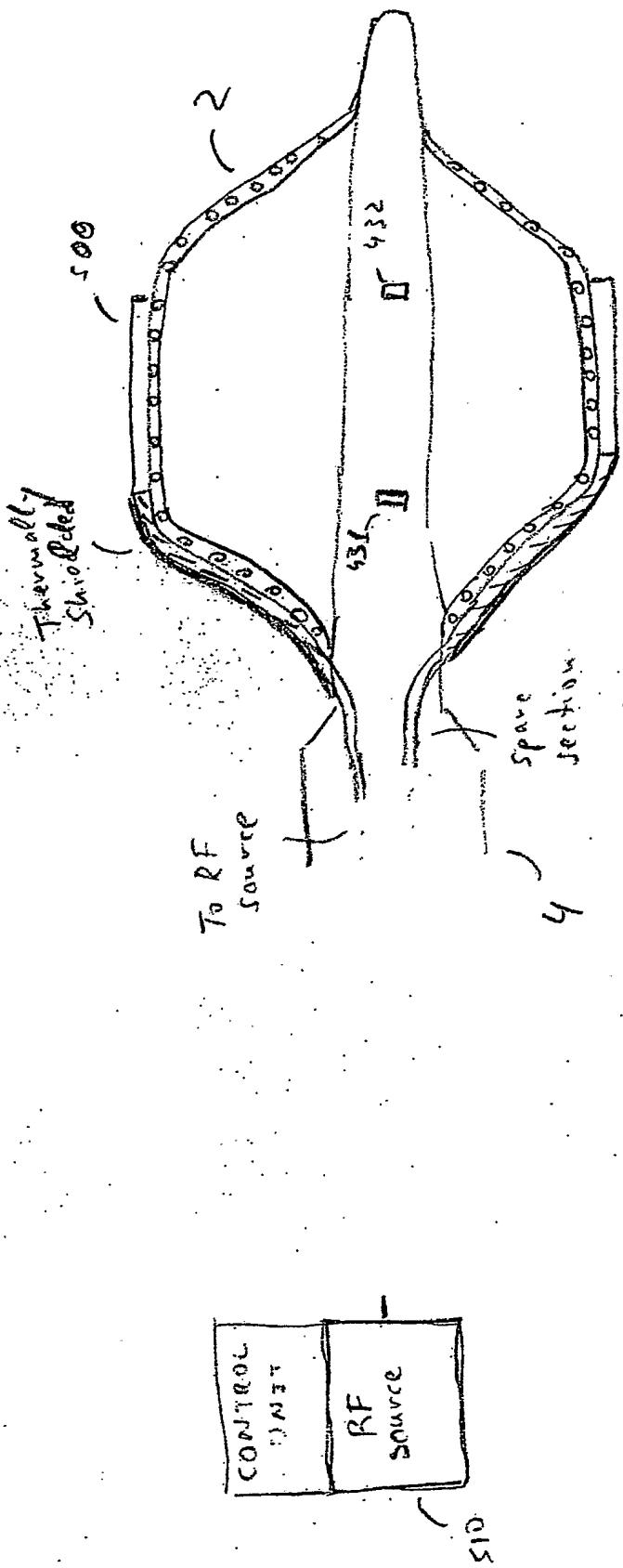


Fig 19c